IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF OHIO

EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL NO. 2804
	:	CASE NO. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES:	:	Hon. Dan A. Polster

\- - -

Friday, January 18, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped deposition of CAROL MARCHIONE, taken pursuant to notice, was held at Golkow Litigation Services, One Liberty Place, 1650 Market Street, Suite 5150, Philadelphia, Pennsylvania 19103, beginning at 9:31 a.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter.

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GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

APPEARANCES:

SKIKOS, CRAWFORD, SKIKOS & JOSEPH, LLP
BY: MARK G. CRAWFORD, ESQUIRE
BY: DYLAN JENSEN, ESQUIRE
One Sansome Street
Suite 2830
San Francisco, California 94104
(415) 546-7300
Mcrawford@skikos.com
Djensen@skikos.com
Representing the Plaintiffs

BRANSTETTER, STRANCH & JENNINGS, PLLC
BY: BENJAMIN A. GASTEL, ESQUIRE
223 Rosa L. Parks Avenue
Suite 200
Nashville, Tennessee 37203
(877) 369-0267
Beng@bsjfirm.com
Representing the Staubus Plaintiffs

MORGAN, LEWIS & BOCKIUS LLP
BY: TINOS DIAMANTATOS, ESQUIRE
77 West Wacker Drive
Chicago, Illinois 60601
(312) 324-1484
Tinos.diamantatos@morganlewis.com
- and -
BY: VINEETA PRAKASH KAMATH, ESQUIRE
1111 Pennsylvania Avenue NW
Washington, DC 20004
(202) 739-3000
Representing the Defendant,
Teva Corporation

APPEARANCES: (Continued)

JONES DAY
BY: SHUBHA M. HARRIS, ESQUIRE
90 South Seventh Street
Suite 4950
Minneapolis, MN 55402
(612) 217-8800
Shubhaharris@jonesday.com
Representing the Defendant,
Walmart

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI
BY: LESLIE A. MARIOTTI, ESQUIRE
1818 Market Street
Suite 3402
Philadelphia, Pennsylvania 19103
(215) 320-6200
LAM@pietragallo.com
Representing the Defendant,
Cardinal Health, Inc.

ARNOLD & PORTER KAYE SCHOLER LLP
BY: WILSON D. MUDGE, ESQUIRE
601 Massachusetts Ave, NW
Washington, DC 20001
(202) 942-5000
Wilson.mudge@arnoldporter.com
Representing the Defendant,
Endo Pharmaceuticals, Endo Health,
and Par Pharmaceuticals

APPEARANCES: (Continued)
VIA TELEPHONE/LIVESTREAM:

REED SMITH, LLP
BY: RYAN K. BLAKE, ESQUIRE
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, Pennsylvania, 19103
(215) 851-8100
Rblake@reedsmith.com
Representing the Defendant,
AmerisourceBergen

ALLEGAERT BERGER & VOGEL LLP
BY: LAUREN J. PINCUS, ESQUIRE
111 Broadway, 20th Floor
New York, New York 10006
(212) 616-7075
Lpincus@abv.com
Representing the Defendant,
Rochester Drug Corporation

ALSO PRESENT:
David Lane, Videographer
Rich Christian, Trial Technician

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(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

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VIDEO TECHNICIAN: We are now on the record. My name is David Lane, videographer for Golkow Litigation Services. Today's date is January 18th, 2019. Our time is 9:31 a.m.

This deposition is taking place in Philadelphia, Pennsylvania, in the matter of National Prescription Opiate Litigation MDL. Our deponent today is Carol Marchione. Counsel will be noted on the stenographic record. The court reporter is Amanda Miller, who will now swear

in our witness.

- - -

CAROL MARCHIONE, after having been duly sworn, was examined and testified as follows:

- - -

VIDEO TECHNICIAN: Please begin.

- - -

EXAMINATION

- - -

BY MR. CRAWFORD:

Q. Good morning.

A. Good morning.

Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation.

Can you please state your name?

A. Sure. Carol Marchione.

Q. And where is your current home and work addresses?

A. They're both the same. And it's

Q. And have you ever had your deposition taken before?

A. Yes, I have.

Q. And about how many times?

A. At least twice.

Q. And what were those cases about?

A. One was for Actiq, a fentanyl product for dental decay. And to be honest, I can't remember what the other one was for.

Q. What was the nature of the Actiq lawsuit?

Was it a lawsuit?

A. I believe it was, yes.

Q. And do you know what the claims were in that suit?

A. The claims were that Actiq caused significant tooth loss, due to the sugar in the product.

Q. And how long ago was that deposition?

A. God. I can approximate, ten years ago.

Q. Okay. So you know -- you're aware you're under oath right now, correct?

A. Yes, I am, I'm aware.

Q. And the deposition is being videotaped?

A. Yes, I am.

Q. And I guess the basic rules, you know to make audible responses, not nodding your head or -- yes or no.

A. I understand.

Q. And if you don't understand a question, please ask me to rephrase it.

A. I will do that.

Q. And take any breaks when you need them.

A. Okay. Thank you.

Q. All right. And you're aware that your testimony here could be used at trial before a jury, correct?

A. That's my understanding.

Q. And if your counsel had asked you if you would appear at a trial in this case, would you be ready and

willing to go to trial to testify?
A. I believe so.
Q. And you're represented here by counsel?
A. I am.
Q. But you're not a current Teva employee, are you?
A. I am not.
Q. And what's your current work position or occupation?
A. I have my own consulting business. So I'm a principal of Marchione and Associates, LLC.
Q. And what does your business do?
A. Regulatory affairs consulting for pharmaceutical companies.
Q. And is Teva or Cephalon any of your current clients?
A. No, they are not.
Q. How about Actavis?
A. No, they're not.
Q. All right.
- - -

(Whereupon, Teva-Marchione Exhibit-1, Resume, Carol S. Marchione, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. We've marked as Exhibit-1 Document 560. But as Exhibit-1, it is a -- appears to be a resume.
Is this your resume?
A. It's an old resume.
Q. Right, okay. And it summarizes your experience here.
Is this -- maybe take a quick look at it.
Does this accurately reflect your work history up to this point, and qualifications?
A. Yes, it does.
Q. And you provide a summary of your experience up at the top. About midway through, it says, Experience includes success with wide variety of FDA regulated mechanisms, such as -- and it

lists RiskMAPs and promotion review, right?
A. Correct.
Q. And what is a RiskMAP?
A. A RiskMAP is the predecessor to what the FDA calls a REMS. So it was a program that was put into place with the FDA to control or -- distribution and sales of products that they have safety concerns. And it's associated with Subpart H, approved products, such as Actiq and Fentora.
Q. And what is Subpart H?
A. Subpart H is a section under 21 C.F.R. 314 which discusses marketing approval of pharmaceutical drugs.
Q. And, you know, what is the purpose or intent of Subpart H?
A. Subpart H is for -- to accelerate approval of life-threatening drugs. That's the intention.
However, usually any drug that they have a concern of safety, they've invoked Subpart H to be able to

control more tightly for -- for postmarketing.
Q. So is it kind of conditions or requirements placed on the company with regard to the drug, to make sure that it is safely used?
MR. DIAMANTATOS: Objection to form.
Go ahead.
BY MR. CRAWFORD:
Q. Would that be a fair characterization?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Generally, yes.
BY MR. CRAWFORD:
Q. And did Actiq and Fentora have RiskMAPs?
A. Actiq had a RiskMAP. And I'm thinking that -- I told you that was the predecessor of REMS.
Fentora, I think, was under a REMS. So it was an evolution, but the

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same principles applied.
Q. All right. And it says, under -- your first positions you list here were Teva Pharmaceuticals, formerly Cephalon, correct?
A. Correct.
Q. And you were there from 2000 until about November 2011, right?
A. No. I was --
Q. Until present, yeah.
So when did you leave Teva?
A. It was 2013, approximately -- I think it was May, around 2013.
Q. All right. And it says one of the accomplishments was successfully negotiated multiple product approvals.
And you list Fentora and Actiq, correct?
A. That's correct.
Q. And are those two drugs, you mentioned that they were under a RiskMAP or a REMS, right?
A. Correct.

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Q. And RiskMAP, what is -- that's kind of an acronym.
What does that stand for, do you know?
A. It's obsolete now, so -- I think it was risk -- I don't know what the "map" stands for now. I just can't remember the exact acronym, what it meant.
Q. How about REMS, what does that acronym stand for?
A. Risk evaluation and mitigation processes or plans --
Q. Strategy?
A. -- strategy plans.
Q. Okay. So risk evaluation and mitigation strategy?
A. That's correct.
Q. All right. And REMS was something that Congress instituted, correct me if I'm wrong, in about 2007 or '08, right?
MR. DIAMANTATOS: Objection to form. Foundation.

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THE WITNESS: I don't remember exactly. But, again, RiskMAP preceded REMS. So I don't know when Congress agreed, or if they agreed. I'm just dealing with the FDA, in terms of their guidances.
BY MR. CRAWFORD:
Q. Is it your understanding that the RiskMAP -- let me strike that.
Is it your understanding that the REMS was a process that the FDA was given power to impose conditions or these plans onto drugs that have already been approved, when, before they had that power, they couldn't -- they couldn't unilaterally do that?
MR. DIAMANTATOS: Objection. Form. Foundation.
Go ahead.
THE WITNESS: So they had the approval when they approved Subpart H, which was back in -- before that. I think it evolved

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since then.
So they had the power in the Act to do that, and the law prior -- when the RiskMAP was in place.
So it evolved, then, the FDA, my understanding, interpreted the guidances and they did -- I understand they got more direction from the Congress from there.
But it started with the Subpart H approval.
BY MR. CRAWFORD:
Q. So let me just try to clarify at least the regulatory standpoint.
A. Sure.
Q. It's my understanding, and let me see if it's also your understanding, that for RiskMAPs, which preceded the REMS programs, RiskMAPs could be imposed with regard -- in conjunction with the approval of a pharmaceutical drug, right?

A. Correct.
Q. But it couldn't be imposed by the FDA after the approval, I guess, unless it was agreed to by the manufacturer, right?
MR. DIAMANTATOS: Objection to form. Foundation.
Go ahead.
THE WITNESS: That's my understanding.
BY MR. CRAWFORD:
Q. And then after the REMS program was put in place, the FDA was given the power to impose that type of risk strategy on a drug that was already approved without getting the agreement of the manufacturer, right?
MR. DIAMANTATOS: Object to form. Foundation.
THE WITNESS: Again, I'm aware of the -- what was in the law in the RiskMAP. I can't be specific about when -- the REMS and how that was associated with

the law.
BY MR. CRAWFORD:
Q. But your understanding was, with REMS, the FDA can impose a REMS without the consent of the manufacturer?
A. Yes, that's correct.
Q. All right. So Actiq and Fentora, those are two drugs.
What period of time was Actiq marketed by Cephalon?
A. I'd say approximately 2001, until Fentora got approved, which was, I don't know, 2010, something around there.
Q. Would 2006 make sense?
A. Yes.
Q. Okay. And then Fentora was approved in 2006, right?
A. Okay, yes.
Q. And it was a drug, by the time you left in 2013, it was still being marketed by Cephalon, right?
A. I don't -- I believe so.
Q. And can you tell me what Actiq was indicated for? What was the

approved indication for Actiq?
A. Actiq was approved for breakthrough -- cancer breakthrough pain in opioid-tolerant patients, for breakthrough, yes, breakthrough pain.
Q. So it was breakthrough pain?
A. Yes.
Q. Was Actiq also approved only for use by cancer patients?
A. Yes.
Q. And tell me what breakthrough pain is.
A. So breakthrough pain are the spikes of intense pain that occur in a -- over time.
Q. And Actiq was intended to treat this breakthrough pain in cancer patients, right?
A. That's correct.
Q. Was -- when Actiq was approved, was it approved to be used in noncancer patients?
A. No.
Q. So you had to have cancer,

really -- well, that was -- the approved indication was for cancer patients' use only, right?
A. That's correct.
MR. DIAMANTATOS: Objection to form.
Go ahead.
BY MR. CRAWFORD:
Q. And can you kind of describe what the product looked like?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: It was a lozenge on a handle, with a tag at the bottom of the handle.
BY MR. CRAWFORD:
Q. And you would stick it in your mouth kind of like a lollipop?
A. That's correct.
Q. And then it would dissolve quickly in the mouth and give you a shot of what, of fentanyl, correct?
A. That's correct.
Q. And that would alleviate the

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pain, the breakthrough pain, right? That was the intent of the product?
A. That's the intention, yes.
Q. And when Fentora was approved -- that was 2006, we decided, right?
A. Yes, I believe so.
Q. And was that -- at the time, do you know if Actiq had had -- the patent had expired for Actiq in 2006?
Do you know if that's the case?
A. I just don't remember.
Q. But Fentora was meant to be kind of a replacement drug, by Cephalon, for Actiq, right?
MR. DIAMANTATOS: Objection to form. Foundation.
BY MR. CRAWFORD:
Q. In the market.
MR. DIAMANTATOS: Same objections.
THE WITNESS: That's my understanding.

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BY MR. CRAWFORD:
Q. And Fentora has, basically, an identical indication as Actiq, right?
A. That's what I remember.
Q. And that was only for use in cancer patients and for breakthrough pain, right?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: In opioid-tolerant, yes, patients.
BY MR. CRAWFORD:
Q. And what do you mean by "opioid-tolerant patients"?
A. Patients who have had -- been exposed previously to opioids and had enough buildup to be tolerant, so they wouldn't -- so there was no lethal adverse events.
Q. So what were the dangers of somebody who wasn't opioid tolerant using the drug?
MR. DIAMANTATOS: Objection. Foundation.

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THE WITNESS: I'm not a physician. But it's respiratory distress, I understand.
BY MR. CRAWFORD:
Q. So -- and how did -- can you explain the mechanism of how Fentora operated?
MR. DIAMANTATOS: Objection. Foundation.
THE WITNESS: Can you explain that question better?
BY MR. CRAWFORD:
Q. Yes.
Actiq was a dissolving lozenge at the end of a stick.
How was Fentora structured?
A. It was a buccal lozenge that you put in your mouth and it disintegrated. So it was similar in process.
Q. It just didn't have a stick on it, right?
A. I think there was a different PK profile, but I don't

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remember.
Q. "PK" stands for?
A. Pharmacokinetic.
Q. So you started at Cephalon in 2000 as director of regulatory affairs.
What were, generally, your responsibilities as director of regulatory affairs from 2000 until December of 2001?
A. I was responsible for the interactions with the Food and Drug Administration for both oncology and -- at that point, the only pain product was Actiq.
Q. And then you were promoted, is that a promotion, to senior director of regulatory affairs from 2002 to 2006, correct?
A. That's correct.
Q. And did your responsibilities change, or were there additional ones?
A. I don't remember. I'm

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sure -- you know, I'm sure something changed, but I don't remember.
Q. But you still had responsibilities for Actiq, correct?
A. I did.
Q. And what were your responsibilities with regard to Actiq as senior director of regulatory affairs?
A. Overseeing submissions to FDA and all communication between the FDA and the company, and to sit on development and commercial teams representing the regulations, the U.S. regulations.
Q. And did you have any responsibilities with regard to the Actiq RiskMAP?
A. I did.
Q. And what were those, that you recall?
A. I was -- there was an annual report -- I'm sorry, there was a quarterly compilation of information to be sent to FDA, and oversight for --

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regulatory oversight for that -- for the RiskMAP.
Q. And would you help prepare that report for the FDA on a quarterly basis, you said?
A. Initially. And then I had a subordinate that I hired to do that.
Q. And who was that?
A. Tracie Parker.
Q. But you maintained overall responsibility for that report?
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: I did.
BY MR. CRAWFORD:
Q. So you would review the reports that went to the FDA after Ms. Parker prepared them?
A. That's correct.
Q. And how was information collected or gathered for that report during these time periods?
MR. DIAMANTATOS: Objection

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to form.
THE WITNESS: We would send out a request document, who was -- the people who were responsible throughout the company, to ask them for information, which they would send and we would compile and review.
BY MR. CRAWFORD:
Q. All right. And then -- what departments, generally, would you get information from?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Medical affairs; commercial; safety; maybe manufacturing, I think; and quality.
BY MR. CRAWFORD:
Q. And "commercial" means the sales and marketing department?
A. That's correct.
Q. So you depend on the accuracy of information that those

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departments provided to you in submitting your report, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That's correct.
BY MR. CRAWFORD:
Q. So would you do anything -- if sales and marketing gave you information to put in the report, would you do anything to verify its accuracy, or would you accept the information your colleagues are providing as being accurate?
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. What was your practice?
A. Right. Quality assurance had the responsibility to check the processes. So I accepted what was received.
Q. And quality assurance, that was a department at Cephalon?

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A. That's correct.
Q. And they would periodically perform audits of these departments to make sure the RiskMAP was properly implemented?
MR. DIAMANTATOS: Objection. Form and foundation.
THE WITNESS: That was their responsibility. I can't say how they did it or when they did it or how.
BY MR. CRAWFORD:
Q. And what -- it's your understanding that it was their responsibility during the period that Actiq, at least, was being marketed?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: That was my understanding. I can't ascertain what exactly happened.
BY MR. CRAWFORD:
Q. So then you were promoted, a promotion, I assume, to senior director

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and group leader, regulatory affairs, from '07 to October 2011, correct?
A. Correct.
Q. And what was -- did your responsibilities change in that position?
A. I can't remember.
Q. And this would have been the period when Fentora was being actively marketed by the company, right?
MR. DIAMANTATOS: Objection. Form.
Go ahead.
THE WITNESS: So Fentora was approved in 2006. I can't tell you exactly, you know, when -- I don't know what month it was approved, but I can assume.
BY MR. CRAWFORD:
Q. All right. So if it was approved in '06, during the 2007 to 2011 period, that's the period that Fentora was being actively marketed by the company, right?
MR. DIAMANTATOS: Objection.

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Form. Foundation.
Go ahead.
THE WITNESS: Yes, I guess. I don't know.
BY MR. CRAWFORD:
Q. Do you know if Actiq was being actively marketed, or had they stopped actively marketing it after they brought on Fentora?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That's not my area. I believe -- I believe that was the case, but I can't say for sure.
BY MR. CRAWFORD:
Q. Right. Thank you.
And then you were promoted, senior director, head of oncology, global regulatory affairs.
That was a promotion, or just a lateral move?
A. It was lateral. Because at that point, I believe the pain area went

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over to somebody else. So I was then just oncology.
Q. Right. Did you have any responsibilities for Actiq or Fentora from November 2011 forward?
A. There was a period of time when they asked me to take over during an interim -- I think when the vice president left or whatever.
But for the most part, I was oncology at that point.
Q. And that doesn't involve the pain drugs?
A. That's correct.
Q. And so you didn't have, unless -- except for this interim period, you didn't have responsibility for Actiq and Fentora?
A. That's correct.
Q. And then you left --
MR. CRAWFORD: Did we get that other document?
MR. JENSEN: No, not yet.
BY MR. CRAWFORD:

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Q. We have a LinkedIn page, we're waiting for a hardcopy, but can we throw that up, and maybe mark it later as Exhibit-2.
MR. DIAMANTATOS: Sure.
MR. CRAWFORD: All right. Let's put up Document 556.
BY MR. CRAWFORD:
Q. I just want to round out your work history, so we pulled that page.
MR. MUDGE: Excuse me, this is Will Mudge, for Endo and Par. Do these documents you're showing have Bates numbers on them, or are they not numbered?
MR. CRAWFORD: The resume was numbered, so I would be happy to read it into the record. The LinkedIn is --
MR. MUDGE: That one, I think, is okay. But just if any of these do have a Bates number, if you could read them, that would

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be very helpful to me.
MR. CRAWFORD: Sure. I would be happy to do that.
BY MR. CRAWFORD:
Q. So we're going to mark, in a second, this document as Exhibit-2, but we have it up on the screen.
This seems to round out your work history, correct?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. At least after Teva?
A. It appears correct.
Q. So the information is accurate on this?
MR. DIAMANTATOS: Objection to the form. Asked and answered.
THE WITNESS: I can't 100 percent -- there's actually -- I checked LinkedIn pretty recently. My current C.V. matches correctly, but I know there's another LinkedIn timeline, so the months

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could be off.
BY MR. CRAWFORD:
Q. All right.
A. But, in general, that's correct.
Q. Thank you for that clarification.
So you left Teva -- is it accurate that you left Teva about April of 2013?
A. That's correct.
Q. And what were the circumstances of your leaving Teva?
A. Teva, which is how I pronounce it, stopped oncology development. And I decided to go consult on my own, because oncology is my strength area. So I wanted to continue doing regulatory for that.
Q. After you left Teva, did you do any work in pain medications?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: One of my

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clients was in the pain area.
BY MR. CRAWFORD:
Q. And what client was that?
A. I'm hesitating because I think there's a confidentiality clause. I don't know if I can relay that.
Q. Well, let's discuss that at a break. So that's fine. Thank you for that.
So you left and you went to Creative Regulatory Solutions for pharmaceutical development and commercialization; is that --
A. That's incorrect.
Q. Okay.
A. The name of my company is Marchione and Associates, LLC.
So that's not my title. That's not my company.
Q. All right. So you became a principal managing director of your own company, at least, from May of 2013 to December 2014, right?
A. I believe that's the -- let

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me see.
Q. Or thereabouts. I won't hold you to the exact month.
A. Approximately, yes.
Q. And then you -- it looks like you moved back into business with TetraLogic Pharmaceuticals from about January of 2015 until some time in early 2016; is that correct?
A. I believe so.
Q. And what particular products were you involved with there?
A. Oncology.
Q. And then you left them again for Inipcocoll Pharmaceuticals, from May of 2016 to about January of 2017; is that correct?
A. That's correct.
Q. And what types of drugs did you deal with there?
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: That was a

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pain product for surgery.
BY MR. CRAWFORD:
Q. And was it an opioid product?
A. No.
Q. And then from January 2018 to the present, you're now principal in your own consulting company that you referenced earlier, right?
A. That's correct.
Q. So we do have the hardcopy, we just marked it Exhibit-2.
- - -
(Whereupon, Teva-Marchione Exhibit-2, LinkedIn, Carol S. Marchione, was marked for identification.)
- - -
THE WITNESS: Thank you.
BY MR. CRAWFORD:
Q. And going back to your resume, it looks like prior to joining Teva, you had been at various pharmaceutical companies prior to July

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2000; it looks like Aventis, Ligand, U.S. BioScience and RW Johnson Research; is that -- back to '91.
Were all of those in regulatory positions with those companies?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. And did you handle any matters dealing with pain products there at any of these companies?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: At McNeil, I worked on the topiramate, which is Topamax, and Tramadol applications. I think topiramate has a pain indication. But Tramadol is definitely pain.
BY MR. CRAWFORD:
Q. And you have a degree, Bachelor of Science in biology in 1998 --

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1980, from Villanova, correct?
A. That's correct.
Q. And any other degrees or graduate degrees?
A. No.
Q. All right. Let's move on here.
MR. CRAWFORD: Actually, I'm going to mark the next document. This will be Document 1554, and also 548. These are a couple of organizational charts. And I will read the Bates number into the record.
Exhibit-3 is Bates TEVA_MDL_A_01861572, and Exhibit-4 is TEVA_MDL_A_01373072.
- - -
(Whereupon, Teva-Marchione Exhibit-3, TEVA_MDL_A_01861562-572, was marked for identification.)
- - -
(Whereupon, Teva-Marchione

Exhibit-4, Org Chart, Regulatory Affairs, 2004, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. So these are -- Exhibit-3 appears to be a corporate org chart for regulatory affairs, dated May 28th, 2003, in the bottom left.

And then what appears to be a different configuration in an org chart dated June 28th, 2004.

Do these charts reflect, to your recollection, the organization of the regulatory affairs departments during these time periods?

MR. DIAMANTATOS: Counsel, excuse me. I don't know that we have the right exhibits on the right Bates, at least I'm not tracking which ones you're looking at.

MR. CRAWFORD: Okay.

MR. DIAMANTATOS: So I have

what's been handed to me, and has also been handed to the witness, Exhibit-4 is a one-page document, the Bates ends in 3072.

MR. CRAWFORD: Okay.

MR. DIAMANTATOS: And I've also been handed, as has the witness, a document which has been labeled Exhibit-3, it's a multipage document.

MR. CRAWFORD: I may have pulled a page out of Exhibit-3. So is there a regulatory affairs page ending in 72?

THE WITNESS: The last page.

MR. DIAMANTATOS: The last page of the document ends in Bates 72.

MR. CRAWFORD: Okay. That will be Exhibit -- that's Exhibit-3?

MR. JENSEN: 4.

MR. CRAWFORD: 4, okay.

MR. DIAMANTATOS: No, I'm

sorry. Exhibit-3 is the one that has the regulatory affairs on the last page of Bates 1572.

MR. CRAWFORD: Okay. We can go with that.

MR. DIAMANTATOS: And the witness also has Exhibit-4, which is the one-page document which ends in 3072.

MR. CRAWFORD: Okay.

MR. DIAMANTATOS: Sorry to interrupt. I just wanted to make sure the record was clear.

MR. CRAWFORD: No, that's good. Thank you. Let's go with that. I must have had something different in my files.

BY MR. CRAWFORD:

Q. So we have Exhibit-3, a chart, starting with TEVA_MDL_A_01861562, clinical research and regulatory affairs.

If you go to the last page, that appears to be the tree where you're located, correct?

A. Correct.

Q. And that is dated May 28th, 2003.

And then Exhibit-4 is the one dated June 28th, 2004, that's TEVA_MDL_A_01373072.

And I just wanted to ask if this, to your recollection, accurately reflects how your departments -- your department was organized within the corporate hierarchy or structure during these times?

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: Yes.

BY MR. CRAWFORD:

Q. And let's start with '03.

So you're listed here as a senior director of regulatory affairs. And you had underneath you, or working for you, Tracie Parker and Susan Williamson, correct?

A. Yes.

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Q. All right. And they were -- were their functions mostly to help you manage the regulatory affairs department?
A. They may have had responsibility for specific drugs, and I oversaw their capabilities.
Q. All right. Good. Thank you.
And then it looks like the position above you is vacant, vice president of worldwide regulatory affairs.
Who was your superior there when you joined the company?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: Oh, God. I can't remember his name.
I'm sorry, I just don't remember his name right now.
BY MR. CRAWFORD:
Q. That's fine. It was quite a while ago.
But do you remember there

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being a vacancy in that position above you?
A. Yes. I remember -- it was Ken, Ken White. Yes.
And Ken White left approximately a year or two after I started. So yes.
Q. And how long did that position stay vacant during this period?
A. You know, I really don't remember.
Q. And it looks like it was eventually filled by Victor Raczkowski; is that correct?
A. That's correct.
Q. If you look at Exhibit-4.
So you reported to Mr. Raczkowski after -- when he filled that position starting at least in 2004, right?
A. That's correct.
Q. And can you walk me through your various -- I mean, was he your superior during the entire time you were

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in the department until you left for the oncology wing?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Yeah, I would need exact dates, because there were -- I had multiple managers. So I would need the exact date.
BY MR. CRAWFORD:
Q. Why don't you just walk me through the chronology of managers?
So you had Mr. Raczkowski, right?
MR. DIAMANTATOS: Objection. Form.
Go ahead.
THE WITNESS: Well, initially I had Ken White.
There was a vacancy where I reported to the chief medical officer temporarily.
BY MR. CRAWFORD:
Q. Who was that?
A. It was originally Paul

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Blake, and then I think he put Leslie Russel underneath him.
And then Victor Raczkowski was there for a couple of years. And then he left and I had -- what was his name -- Eric Floyd for about two years, and he left.
And then I had Jim Ottinger by the time I left.
Q. How do you spell Ottinger?
A. O-T-T-I-N-G-E-R.
Q. And where were -- where was Mr. Raczkowski based? Was he in your office?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: Yes, he was in Malvern at the time.
BY MR. CRAWFORD:
Q. And that's where you were located, Malvern?
A. That's correct.
Q. And were you in Malvern the entire time you were there at Cephalon

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and Teva?
A. No.
Q. Give me what offices you were in and when you switched.
A. Initially when I started in 2000, the office was in West Chester. And then we moved offices across the street for a year, or whatever.
And then we moved to Malvern. And that's pretty much the whole time I was there, from that point on.
Q. So your superiors were always in the same office you were?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. Except for the interim period, maybe?
A. That's correct.
Q. And looking at Exhibit-4, it looks like you still have Tracie Parker underneath you. And then you now have Penny Levin, Ruth Kearns and Darren

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Dorman below you.
Did they -- were those three added after the -- May of 2003 to your department?
A. I believe so.
Q. And did they assist you with various products in the regulatory aspect?
A. Yes.
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. And during this period, you had responsibility for Actiq, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That is correct.
BY MR. CRAWFORD:
Q. All right. That's all I had on those.
Now, Cephalon was acquired

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at some point by Teva, correct?
A. Yes.
Q. And that was around 2011?
A. I believe so.
Q. And remind me, is that about the time that you switched to oncology, right, 2011?
If you look at Exhibit-1, that might refresh your recollection.
A. You showed me the -- yes. Thank you.
2007 is when I became head of oncology.
Q. Oh, okay. No. I don't think that's accurate here.
I think it was November 2011 you became head of oncology, right?
A. No.
Q. Okay. So you were senior director and group leader, regulatory affairs, from 2007 to 2011, right?
A. I was senior director and group leader, it says -- let me get my glasses -- 2007 to 2011, that's correct.

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Q. And so then you moved to head of oncology in November 2011, right?
A. That's correct. Sorry.
Q. And do you know who succeeded you in the position -- regulatory affairs position that oversaw Fentora?
A. I don't remember. Maybe Penny Levin may have taken that responsibility. I just don't remember.
Q. Do you remember when -- after the acquisition, was there a counterpart regulatory person at Teva that you interacted with?
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: For, specifically, you mean, as a manager?
BY MR. CRAWFORD:
Q. That was a bad question. So I'll withdraw it.
I'm trying to find out, so

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when Teva took over, there was -- obviously, was there any kind of merger of operations at all with Teva USA and Cephalon?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: No, not really. There was -- there could have been some reorganization. I just don't remember.

Things went back-and-forth numerous times, so that's why it's difficult for me to remember when and who and exactly --

BY MR. CRAWFORD:

Q. Right. Did Teva bring in any of their regulatory people into your department at all after the acquisition?

A. Yes.

Q. Do you remember who that was?

A. Mike -- what was Mike's last name? He came from Teva and he reported to me. What's Mike's last name?

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And, yes, there were different people that were brought in.

Q. And when Teva purchased Cephalon, did Teva have its own opioid products, pain products?

MR. DIAMANTATOS: Objection to form. Foundation.

BY MR. CRAWFORD:

Q. Generic?

MR. DIAMANTATOS: Objection to form. Foundation.

THE WITNESS: I don't -- I don't know. I didn't interact with the generic group. I can't tell you.

The generic group was separate when I was there.

BY MR. CRAWFORD:

Q. Do you know who was head of regulatory or in the regulatory department for Teva after you guys joined?

MR. DIAMANTATOS: Objection. Form. Foundation.

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Go ahead.

THE WITNESS: I believe when they merged, I think Jim Ottinger, who was head of branded products, became head of at least branded, and then eventually I think he took over generic also.

BY MR. CRAWFORD:

Q. And was he already with Teva --

A. No. He was hired -- I don't know exactly what year, but he was hired in.

Q. After the merger?

MR. DIAMANTATOS: Objection. Form. Foundation.

THE WITNESS: I'm not exactly sure which -- the date or when that was.

BY MR. CRAWFORD:

Q. And after Teva acquired Cephalon, did you become an employee of Teva, or did you stay an employee of Cephalon?

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A. An employee of Teva.

Q. And what Teva entity employed you? Do you know the name?

A. Teva Pharmaceuticals.

Q. What was the full name? Teva Pharmaceuticals USA, or do you know?

A. I think it was just Teva Pharmaceuticals.

Q. All right. Do you recall what your compensation was at the time you left Teva?

A. I'd approximate it to be about 270 a year.

Q. And about what was it when you started?

A. All the way back in 2000? I don't know. I'd approximate it at 125.

Q. And did you receive bonuses or stock options as part of your compensation?

A. Yes.

Q. And was that on a yearly basis while you were there?

A. Generally.

Q. And what were those bonuses based on? Your bonuses and your stock options, what were they based on?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. What type of performance?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I believe that --
MR. CRAWFORD: Strike that.
BY MR. CRAWFORD:
Q. Were they performance-based, the bonuses and stock options?
A. Yes.
Q. And what were the criteria for determining how much you would get?
MR. DIAMANTATOS: Objection. Form. Foundation. Time frame.
THE WITNESS: So it differed by time frame.
BY MR. CRAWFORD:
Q. Just walk me through from

when you started until you left Teva, what you can remember, as far as the criteria.
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I think when I began, my initial level, it could have been a bonus was maybe 25 percent of my salary. And I think it went up -- this was the target -- it was approximately 32 percent.
But that was based upon not just my performance, the department performance and then the company performance. So there was an algorithm.
BY MR. CRAWFORD:
Q. And how was your department performance measured?
MR. DIAMANTATOS: Objection. Form. Foundation.
BY MR. CRAWFORD:
Q. If you know.

A. Every year there were objectives, and if you met the objectives.
Q. And then the company performance, what was that based on? Its revenues or profits? Was that any of the criteria?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: Company objectives -- there was company objectives, department objectives, and then my personal objectives.
BY MR. CRAWFORD:
Q. So that was your understanding of what your bonus and stock option awards were based on?
A. That's correct.
Q. And would this have been the entire time period you were there, or did it change?
A. That's my recollection.
Q. And then when you left the company, we did take a look at your

personnel file, and it looked like you had gotten a $50,000 bonus in February 2012; an $87,000 in March of 2013; a $260,000 payment in May of 2013; and even after you left, we saw a $29,000 pay stub.
Are these amounts that seem in line with what your recollection is?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: It sounds about right.
BY MR. CRAWFORD:
Q. And so the $260,000 payment in May of 2013, was that considered a severance-type of payment? Or what was the basis of that payment?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That was a severance.
BY MR. CRAWFORD:
Q. And then the $87,000 bonus in March of 2013, what was that based on?

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A. That was the annual bonus.
Q. And the $50,000 bonus in February 2012, that, again, was the annual bonus?
A. That's correct.
Q. And in addition to these cash bonuses, you could get -- or you did get stock options, too, correct?
A. That's correct.
Q. And approximately -- is there any way to quantify the stock options you received towards the end there?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I really don't remember --
BY MR. CRAWFORD:
Q. Number of shares or value?
A. -- because there were grant options. It's so complex, I couldn't understand it from year to year. So I can't remember it right now. Sorry.
Q. Do you currently own Teva

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stock?
A. No, I do not.
Q. And it was granted in Teva stock, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: It depends what year you're talking about.
BY MR. CRAWFORD:
Q. So before Teva acquired Cephalon, was it Cephalon stock that you were given options?
MR. DIAMANTATOS: Objection. Form. Assumes facts.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. Yes?
A. Yes.
Q. And then after Teva acquired Cephalon, were the stock options for Teva stock?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I believe so.

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BY MR. CRAWFORD:
Q. And now do you own any Cephalon or Teva stock?
MR. DIAMANTATOS: Objection. Form. Asked and answered.
THE WITNESS: No, I do not.
MR. CRAWFORD: Let's pull up Document 596 and mark the next exhibit.
- - -
(Whereupon, Teva-Marchione Exhibit-5, TEVA_MDL_A_08242688-693, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. So what we've marked here as Exhibit-5 is a -- it looks like it's stamped November 4th, 1998 letter from the Department of Health and Human Services to Anesta Corporation. And it's document TEVA_MDL_A_08242688.
And this appears to be the approval letter for Actiq.

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Is that what this looks like to you?
A. Give me one second.
MR. DIAMANTATOS: Objection. Foundation.
THE WITNESS: That's my understanding.
BY MR. CRAWFORD:
Q. And Anesta Corporation was purchased by Cephalon some time before you arrived at Cephalon, correct?
A. That's correct.
Q. And Patricia Richards, was she at all in your department or at your company when you joined Cephalon?
A. No.
Q. So this letter, go down to the third paragraph. It says, This new drug application provides for the use of Actiq for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

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Is that your understanding of what the approval -- the indication was for Actiq that was approved by the FDA?

A. In general. Sometimes the actual labeled indication is slightly different.

Q. All right. But you do understand that it was approved only for patients who had cancer, malignancies, correct?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: That's what it says here, yes.

BY MR. CRAWFORD:

Q. Right. But that's your understanding of, ultimately, what it was approved for, or at least one of the conditions, right?

MR. DIAMANTATOS: Objection to form. Asked and answered.

THE WITNESS: Yes.

BY MR. CRAWFORD:

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Q. It then says, in the next paragraph, We have reviewed this application under the restricted distribution regulations contained in 21 C.F.R. 314.520, Subpart H, and have concluded that restrictions on distribution and use of Actiq are needed to assure safe use of the product.

So this was the Subpart H you were referring to, correct?

A. Yes.

Q. And then they state that, We have completed the review of this application, including the Actiq risk management program, RMP, as amended. We have concluded that adequate information has now been presented to demonstrate that Actiq is safe and effective when marketed in accordance with the terms of restricted distribution and use described in the risk management program.

So is it your understanding that, in order for, in the FDA's view -- and this is just how you understood at

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the time -- in the FDA's view that the risk management program was essential to be implemented for the safe use of the product?

MR. DIAMANTATOS: Objection to the form. Foundation. Calls for speculation.

THE WITNESS: So you're asking me for the FDA's view. And what you just asked me is written clearly here, so I'm assuming that that's the case.

BY MR. CRAWFORD:

Q. But you understood that in order for Actiq to be a safe drug, it needed to be marketed in accordance with the RiskMAP?

MR. DIAMANTATOS: Objection. Form. Foundation.

THE WITNESS: That wasn't necessarily my determination. But what I'm understanding is that the FDA has deemed that.

BY MR. CRAWFORD:

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Q. All right. Thank you.

And then if you can go to the next page, referencing changes to the Actiq risk management program, it says, Please note the attached risk management program, RMP, is an integral part of the approved NDA for this product and is an essential component of the terms of this NDA's approval by the FDA for marketing this product in the United States. As such, any proposed changes in the risk management program must be submitted to FDA as a supplement to the NDA, and any proposed change must have FDA prior approval before implementation. Changing the risk management program without prior FDA approval may render the product misbranded and an unapproved new drug.

So reading that, does that refresh any recollection that if the RiskMAP was going to be changed by the company, you needed FDA approval first before implementing those changes?

MR. DIAMANTATOS: Objection.

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Form. Foundation.
THE WITNESS: There was significant communication with the FDA. We tried many, many times, over the course of years, to revise the RiskMAP, and they would not provide us feedback. We submitted supplements, they never answered it.
So it got to the point there were administrative issues that we had to change. So I communicated. I wrote to them. I finally said that we need to change -- not we're not changing any fundamental issues, but because of the administration issues that we have to acknowledge, we were changing and please let us know as soon as possible.
And you'll find that in the documentation.
BY MR. CRAWFORD:
Q. Did they ultimately ever

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approve any supplements for any changes in the Actiq RiskMAP?
MR. DIAMANTATOS: Objection. Form. Vague. Foundation.
THE WITNESS: I don't believe they ever did, to be honest.
BY MR. CRAWFORD:
Q. Was there one change -- and I just remember looking through the records -- where I think you submit some type of supplement changing the name of the sales force or something that detailed the drug?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I know I did at least one. And then it got to be, again, multiple communications, e-mails. I'd have to estimate ten to fifteen communications were done where they would not respond to the changes we requested.

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And so from that point on, when I submitted a quarterly that had a change, let's say, it went to -- you know, Walmart to Walgreens or something like that, I had to say, this is a change and we're acknowledging it's administrative, but it's not substantively changing the RiskMAP.
And we had to do it that way because we couldn't get communication back.
BY MR. CRAWFORD:
Q. But you agree, at least in the beginning, the FDA is saying, in order to get a change or before implementing it, you have to get our prior approval, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.
THE WITNESS: That's what it says here.

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BY MR. CRAWFORD:
Q. Do you know why the FDA was not acting on any proposed changes that you say were being made or asked -- requested?
MR. DIAMANTATOS: Objection. Form. Calls for speculation. Foundation.
THE WITNESS: No, I do not.
BY MR. CRAWFORD:
Q. If you could turn to Page 692 at the bottom.
A. Got you.
Q. They are stating here, the FDA, in the letter to Anesta, In addition, please note that this product is only -- has been approved only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. As such, please note the promotional statements or representations by you that this product

may, indeed, be safe and efficacious in the treatment of diseases or patient populations beyond that contained in your approved labeling may be considered a violation of the Act.

So does that comport, as a person, as somebody with regulatory background, with what the rules are with regard to promoting a product, an FDA-approved product?

MR. DIAMANTATOS: Objection. Form.

Go ahead.

THE WITNESS: Yes.

BY MR. CRAWFORD:

Q. And when you joined Cephalon in the regulatory department, would it have been your practice to go back and look at the initial approval files of the drug that you -- drugs that you were working with?

A. If something required it, yes.

Q. Do you believe that you may

have reviewed this letter at any time?

A. Yes.

Q. And do you believe you would have reviewed it early in your tenure there at Cephalon?

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: Yes.

MR. CRAWFORD: All right. Let's go to the next document here.

MR. JENSEN: Exhibit-6.

MR. CRAWFORD: This doesn't have a Bates number.

- - -

(Whereupon, Teva-Marchione Exhibit-6, No Bates, 1998 21 CFR 314.520, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. I pulled 314.520, which that was the section referenced on Page 1 of

Exhibit-5, the approval letter, right?

A. I believe so, yes.

Q. And is that Subpart H right here, or at least part of it?

A. It's part of it.

Q. And I tried to pull the version back in 1998. I don't know if it's changed.

But it does say, If the FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as needed to assure safe use of the drug product.

So is that your understanding of what Subpart H and the FDA is requiring when they approved Actiq?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: They invoked that subsection of Subpart H when they approved Actiq.

BY MR. CRAWFORD:

Q. Right. So the FDA there was requiring the RiskMAP to assure that the drug would be safely used, Actiq, right?

MR. DIAMANTATOS: Objection. Form. Foundation.

BY MR. CRAWFORD:

Q. Under Subpart H, in your understanding?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.

THE WITNESS: I'm sorry, can you repeat the first part of that question?

BY MR. CRAWFORD:

Q. We got kind of interchanged there. I'd be happy to do that.

I'm just -- now that you've seen the letter and you've seen, actually, the text of Subpart H that at least we pulled here, is it your understanding that the FDA -- that a drug approved under Subpart H imposes

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conditions to ensure that the drug that is approved under that section would be used safely?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That it would be restricted to -- I'm sorry, the question was a little awkward.
BY MR. CRAWFORD:
Q. Well, what's your understanding of -- now that you've read this section, you've read the letter, what was your understanding of the FDA's views on -- on the necessity of the RiskMAP being approved to assure the safe use of Actiq?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: So if -- that it was approved under limited distribution and restrictions, and it's -- what's missing here is, under the big scope of Subpart H,

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is that if it's not, then it can be -- then it gives the FDA the authority to then pull back the approval.
And that's -- you're missing that section here. But that's the intention.
BY MR. CRAWFORD:
Q. Thank you for filling that in. All right.
MR. CRAWFORD: 601 next.
MR. JENSEN: This will be Exhibit-7.
- - -
(Whereupon, Teva-Marchione Exhibit-7, TEVA_MDL_A_03272088-117, was marked for identification.)
- - -
MR. CRAWFORD: What we marked here is a document entitled, Risk Management Program for Actiq, which is referenced in the top. And then lists the drug

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sponsor as Anesta Corp., a subsidiary of Cephalon, Inc. And the date on the lower right is February 9, 1999. The document number is TEVA_MDL_A_03272088.
BY MR. CRAWFORD:
Q. Was this the RiskMAP that you recall that was in place when you joined the company, for Actiq?
A. No. When I joined, it was still under Anesta. And so we must have submitted this after I joined.
Q. I see.
So this was in place, at least, early in your tenure there?
A. Yes.
Q. But you joined -- you joined Cephalon in 2000, right?
A. That's correct.
Q. And this is dated February 9, 1999, and it does reference Cephalon.
But this is basically the one that you were operating under when you were there?

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A. So it does have --
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: It does have February 9, but the August 1st is telling me -- so the issue is, going back to the approval letter, if a single word changes, the FDA would then need approval.
So this is an instance where we tried to keep the date -- we tried to minimize any changes whatsoever, because it wasn't yet approved and the FDA wouldn't approve it.
So that's why you have two dates on this. We added a separate date, but we didn't want to change the February 9th date because -- because every single letter was considered a change.
Does that make sense?
BY MR. CRAWFORD:

Q. Yes.
Is it your understanding, though, that this version, at least, was approved by the FDA?
A. No, it was not.
Q. So you're saying that the February 9th, 1999 one is the approved one?
A. Probably, yes.
Q. All right.
MR. CRAWFORD: Let's take a quick break, if we can.
VIDEO TECHNICIAN: Going off the record at 10:34 a.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 10:46 a.m.
BY MR. CRAWFORD:
Q. All right. We took a look, and I think we found the February 9th, 1999 RiskMAP. So we're getting copies

made, and we'll mark that -- we're going to mark it as Exhibit-8 once we get it, and then we'll give you an opportunity to take a look at it. So I won't ask you anything about it right now.
Let's proceed on with Exhibit-7. This essentially was the RiskMAP version that you were working off of when you -- after you arrived at Cephalon, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I believe so.
BY MR. CRAWFORD:
Q. Okay. So I'd like to delve into this.
On Page 5, under introduction, it says, The Actiq risk management program, RMP, has been designed to address three potential risk situations.
And one risk situation, you'll agree with me, is diversion and abuse, correct?

A. Yes.
Q. And the goal, it states, is the primary goal of making every reasonable effort to reduce the risk of potential untoward events in the unintended populations, to the extent possible. This program includes the following -- and then skipping down -- comprehensive, professional patient caregivers and child educational programs, interventions at the point of dispensing, and Class II status for Actiq.
So was it your understanding, as well, that the goal of this program was to reduce the risk of untoward events in unintended populations?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.
THE WITNESS: That was one of three reasons.
BY MR. CRAWFORD:

Q. What was the one reason --
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. -- that you're referring to?
A. What you just -- what you just -- I'm going back to your question.
Q. Right.
A. I'm sorry, can you repeat it?
Q. I think you're right.
There were basically three reasons for the RiskMAP program. One of them was for prevention of diversion and abuse, correct?
A. That's correct.
Q. So I think that's the main focus I'm going to have with regard to looking through this. I don't want to go through every single word of it, so I'm going to kind of direct more towards that reason.
Below that, it says, This document provides details and

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implementation tactics for all elements of the Actiq risk management program. No single element can provide the complete answer to reducing risk. A lengthy series of events must occur in sequence before a risk can occur, yet any one of multiple RMP elements can intervene to interrupt the sequence and prevent the risk event. Redundancy of program elements is one measure used to strengthen the effectiveness of the RMP. The purpose of the RMP is to ensure the safe use of this product.

So is it your understanding that the RiskMAP was -- had a, I would say, elements, redundant elements, to make sure that Actiq was used safely?

MR. DIAMANTATOS: Objection to form. Foundation. Speculation.

THE WITNESS: That was the -- that's what the FDA said the intention of this document was, yes.

Page 91

BY MR. CRAWFORD:

Q. And do you believe, when you were -- you were in charge of collecting up information and submitting quarterly reports to the FDA about how things were progressing with regard to the operation of the RiskMAP, right?

A. That's correct.

Q. And so you -- was it your understanding that the RiskMAP contained certain elements and programs that were redundant to try to prevent any untoward effects from the drug?

MR. DIAMANTATOS: Objection. Form.

THE WITNESS: That was the FDA's intention.

BY MR. CRAWFORD:

Q. Okay. And your job was to make sure that the company was -- one of your jobs was to make sure that the company was trying to implement those mechanisms, right? Or at least report to the FDA about how the company was doing?

Page 92

A. That's correct. Reporting to the FDA, yes.

Q. But other departments, it was their job to make sure these elements were implemented, right?

A. That's correct.

Q. And that would include sales and marketing, right?

A. That's correct.

Q. And they would report to you how they were doing in complying with the RiskMAP, and you would assemble that, or your underlings would, into a report to the FDA?

A. That's correct.

Q. All right. Good. Fair enough.

It does say, There are key messages for the RiskMAP. There are several key messages repeated throughout the RMP, which are listed below.

Proper patient selection and prevention of diversion and abuse messages look like they are some of the

Page 93

messages that the FDA wanted to convey, right?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

THE WITNESS: That's what it says --

BY MR. CRAWFORD:

Q. According to this letter?

A. According to this document.

Q. Right. And one of the proper patient selection messages listed on the next page, under the second bullet point, is that, Actiq is specifically indicated solely for the treatment of breakthrough cancer pain in chronic opioid-tolerant patients.

Is that one of the messages the FDA wanted the company to convey?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

THE WITNESS: That's what this document says, yes.

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BY MR. CRAWFORD:
Q. And also for prevention of diversion/abuse messages, the FDA wanted the company to convey that Actiq may be habit forming, right?
MR. DIAMANTATOS: Objection to form. Calls for speculation.
THE WITNESS: That's what this document says.
BY MR. CRAWFORD:
Q. And then it references, too, under that bullet point there, that Actiq is a Class II medication, right?
A. That's what this document says.
Q. Is it your understanding that Actiq was a Class II medication?
A. Yes, it was.
Q. Let's go to Page 9 of the RiskMAP, at the bottom, under labeling.
And then it says, C-II, Schedule II, Classification 3.1.
It says, Actiq will be a C-II product, consistent with other

Page 95

strong opioids such as fentanyl, morphine, Oxycodone and hydromorphone-based products. C-II is the most restrictive classification available, and raises the overall level of vigilance and surveillance by all parties involved with the product.
So was it your understanding that the FDA -- well, let's hear, what is your understanding of what a Class II product is and what restrictions are imposed upon it?
A. The details of that is more for DEA people. I was more focused on the restrictions from under the RiskMAP.
So I think there's particular levels of people who can prescribe C-II. I don't know all the details, because it's not my area of expertise.
Q. Understood.
So the FDA wanted the Schedule II classification to be another tool, probably a redundant tool, to make

Page 96

sure it was used safely, right?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.
THE WITNESS: That's what it says in this document, yes.
BY MR. CRAWFORD:
Q. And what you're saying is there was another department within Cephalon that -- that was in charge of DEA compliance, right?
MR. DIAMANTATOS: Objection. Form. Mischaracterizes the witness's testimony.
THE WITNESS: What I was saying is I don't know the specifics of the requirements under the C-II. And there was another department that would oversee that.
BY MR. CRAWFORD:
Q. All right. So that was the -- was it called the compliance department or DEA compliance department?

Page 97

A. I don't know the formal name. But yes.
Q. That was their basic function --
A. I believe so.
Q. -- was to ensure that the company was complying with all the Class II requirements?
A. That's my understanding.
Q. Right. And do you know who was in charge of that department?
Was it Colleen McGinn? Does that name seem familiar?
A. It seems familiar.
Q. And would they -- would the DEA compliance department, or whatever it's called, when you put your quarterly reports together, would they be one of the departments that would provide you with input?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I believe so. I'd have to remember the

Page 98

specifics. It's been a while.
BY MR. CRAWFORD:
Q. But your department, or you personally, didn't have any responsibility for making sure that the company was complying with the Class II or DEA requirements, right?
A. That's correct.
Q. But it is a component of the RiskMAP, so it would be part of your reporting to the FDA regarding the Class II issue?
A. I don't remember exactly what had to be reported for that. I'd have to look at this.
Once it's scheduled, it doesn't change. So it may just be acknowledging that it has to be scheduled.
Q. Yeah, let's move on. And if you see something that had to be reported about it, why don't we flag that?
A. That's fine.
Q. Fair enough.

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So the next page, it says, right after the bullet points, The status of Actiq -- is it pronounced Actiq or Actiq? How do you pronounce it?
A. Officially, it was Actiq.
Q. All right.
So the status of Actiq as a C-II product is the primary risk management element that a third potential risk event, the potential of diversion on/or abuse -- I don't think I read that right. Start again.
The status of Actiq as a Class II product is the primary risk management element against the third potential risk event - the potential for diversion and/or abuse.
So is it your view that the RiskMAP that you were involved with understood that the Class II classification was an important element, a primary element, for making sure that the drug was not abused?
MR. DIAMANTATOS: Objection.

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Form. Foundation.
THE WITNESS: I think it was one of the elements. I wouldn't say it was the primary.
BY MR. CRAWFORD:
Q. Again, there were redundant elements to try to make sure that the drug was used as safely as possible in the RiskMAP, right?
A. That's correct.
Q. Let's go to Page 12.
Under 4.1, Key Message Points, the RiskMAP states, The education of physicians, nurses, pharmacists, caregivers and patients on the safe use of Actiq is an integral part of the Actiq risk management program.
Again, it was your understanding that that was an integral part of the RiskMAP and the company's obligations, right?
A. What was? The educational program?
Q. The education of doctors --

Page 101

A. Yes.
Q. -- nurses, pharmacists, et cetera, right?
A. That's correct.
Q. And one of the messages was prevention and diversion of abuse messages, right?
A. That's correct.
Q. And then the educational programs for physicians, nurses, pharmacists, caregivers and patients will also reinforce the following.
One point is efficacy and side effects of the product, right?
A. That's correct.
Q. And then turning to Page 13, it says, These key educational messages, primarily focusing on safety, are provided to the physicians, nurses and pharmacists through the communication vehicles which are discussed on the following pages.
Do you understand what the RiskMAP means by "communication vehicle"?

Page 102

A. Yes.
Q. So they are listed here.
One would be Actiq speakers bureau medical education programs, right?
A. Yes.
Q. And the goal of those programs, under the RiskMAP, would be to educate doctors on these messages that we just went over, correct?
A. I'm just reading this. Give me one second.
I'm sorry, can you repeat the question again? I'm sorry. I just wanted to read that section before --
Q. Please do. If you need to read something, take your time to do that.
A. So if you could ask the question again.
Q. Sure.
And the goal of the programs under the RiskMAP would be to educate doctors on these messages that we just went over, correct?

Page 103

A. That was one of the -- that was one of the elements, to get the risks -- the information on the risks out. It was a tool.
Q. Right. So the idea is to use these speakers programs to educate doctors on the risks and the messages that are outlined in the RiskMAP, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: So as I'm reading this, they want to train professionals to train others. So it was kind of a two-level element.
That's why I was trying to be clear.
BY MR. CRAWFORD:
Q. Right. It says those people that are trained, these groups, will then be called upon to educate the respective peers and patients, via presentations in local, state, regional and national settings, correct?

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A. That's correct.
Q. That was at least what the RiskMAP -- the RiskMAP, it was required by the FDA, but it's something that Anesta, and, I guess, the subsequent NDA holders, were agreeable to doing, right?
Or was this just something done because you were told to do it?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: By taking over the NDA, we had to agree to do this, yes.
BY MR. CRAWFORD:
Q. And take over those responsibilities?
A. That's correct.
Q. Okay. Thank you.
And then one of the other communication vehicles would be publications, under 4.4, correct?
A. That's what it says here.
Q. Right. And the

Page 105

publications, it says, will include messages that reinforce elements of the RiskMAP, right?
A. That's what it says here.
Q. And then it lists a number, in the next few pages, of publication communication vehicles that the company might utilize to get across its messages.
Is that how you understood the program was to operate?
A. That's what it says here.
Q. But this is a program that was intended to ensure the safe use of Actiq, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
BY MR. CRAWFORD:
Q. Help ensure, anyway?
A. Help ensure, yes.
Q. Right. All right. Under Page 15, 5.0, Actiq Launch Program, the RiskMAP states, Actiq will target a relatively small group of clinicians. The emphasis of the promotion will be

Page 106

highly educational.
That's what was intended in promoting the drug, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
BY MR. CRAWFORD:
Q. Through the RiskMAP?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: This talks specifically at launch, yes.
BY MR. CRAWFORD:
Q. But even after launch, did -- was the education supposed to stop or was that supposed to continue throughout the marketing of the drug?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: I just wanted to find where else it mentioned that. Because you just directed me to this section for launch.

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BY MR. CRAWFORD:
Q. All right. Take your time, too. I don't want to rush you through this.
A. So this document specifically says at launch. The interpretation, I believe, is to take it beyond that.
Q. Right. The educational would be messages to doctors?
A. But it's not specified in the RiskMAP, in the REMS or RiskMAP.
Q. But the intent is that the educational aspect will continue even after launch --
MR. DIAMANTATOS: Objection to form. Foundation.
BY MR. CRAWFORD:
Q. -- in your view?
MR. DIAMANTATOS: Calls for speculation.
THE WITNESS: It's not written in here that way. So it was -- I believe it was the

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interpretation of the company.
BY MR. CRAWFORD:
Q. All right.
A. I can't say for -- you know, it's not specified.
Q. All right. Let's go to the next page, 16.
It talks about the oncology sales specialists. Cephalon, Inc. sales organization, full-time oncology sales specialists have been placed in the field to personally call on the target audience. The oncology sales specialists are the primary day-to-day link to the physicians, nurses and pharmacies who will be using the product. The oncology sales specialists play a key role in implementing the RiskMAP.
Now, your understanding that in implementing this RiskMAP plan, that the sales representatives would play a key role in disseminating the RiskMAP messages.
A. That's what it says in this

Page 109

document.
Q. And it does say oncology sales specialist there.
Cephalon didn't really have an oncology sales specialist, did it --
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. -- at the time?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. They were more the pain detailing people, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I don't remember the exact title, but it was a different -- they had different titles than this.
BY MR. CRAWFORD:
Q. But it would still mean that -- whatever the name was of the sales specialists, the intent was that they would -- when they called upon

Page 110

doctors to promote the drug, they would be the ones to convey the RiskMAP messages, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: That's implied, but it doesn't specify it in the document.
BY MR. CRAWFORD:
Q. Because it's a different name?
A. Exactly.
Q. I think, and I could be wrong, but I think there was actually a supplemental change that the FDA approved to change the name of the specialists.
Do you recall that at all?
A. I don't know -- I don't know -- I was trying to remember if they approved any of it. So I just don't remember.
I know we submitted the change. But I just don't remember if it was approved.

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Q. All right. Thank you.
Page 21, part of the RiskMAP, under 7.0, is that product samples will not be made available.
Do you know why that was an important component of the RiskMAP?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.
THE WITNESS: I don't know what was in the FDA's mind, why they specified that, to be honest. I can't say what they were thinking.
BY MR. CRAWFORD:
Q. Okay. But you know that this plan prohibited the dissemination or providing of samples of Actiq, right?
A. That's what it says here, yes.
Q. And would that include providing coupons or vouchers to get free samples of the product --
MR. DIAMANTATOS: Objection.

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Form.
BY MR. CRAWFORD:
Q. -- in your view?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: No, not necessarily.
BY MR. CRAWFORD:
Q. How is that different than providing samples?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: Because it could be controlled better than just handing out samples. So it's a more controlled distribution.
BY MR. CRAWFORD:
Q. All right. Moving on to Page 22, 8.0, Surveillance goals and activities.
The goals of the Actiq surveillance and monitoring program are to determine the effectiveness of the Actiq risk management program by

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monitoring the potential incidence and outcome of child accidental ingestion, potential product use among opioid nontolerant populations, off-label use, and possible diversion and abuse; trigger interventions when problems are discovered; and make modifications to the Actiq risk management program to improve its effectiveness.
So it was your understanding that, as part of this program, there was some kind of surveillance and monitoring program in place?
A. Yes, there was.
Q. And what department was that run out of?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. Was it quality assurance?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: Safety had, for instance, had its own

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processes; if they heard something, they would respond. So each stream of processes had evaluation by the initial department, and then quality would then check on that process.
BY MR. CRAWFORD:
Q. And to initiate modifications, if the company saw that there was some shortcomings in the program, it was free to make modifications, so long as they submitted them to the FDA and they were approved, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That was the interpretation of this document.
BY MR. CRAWFORD:
Q. And, again, one of the objects -- or goals of the Actiq surveillance monitoring program was to monitor the off-label use of the product, right?

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MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: That's what this document asks for, yes.
BY MR. CRAWFORD:
Q. And this is a document that the company was required to follow as a condition for continued -- being allowed to continue to market Actiq, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. And off-label use means -- what does that mean to you?
A. That means it's documented that somebody who doesn't meet the labeled criteria is using the product.
Q. So if somebody -- off-label use might be somebody who is a noncancer patient that used the product; that would be off label?
MR. DIAMANTATOS: Objection.

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Form. Mischaracterizes the witness's testimony. Foundation.
THE WITNESS: Can you repeat the question again?
BY MR. CRAWFORD:
Q. Yes.
So somebody who used the drug who didn't have cancer, that would be an off-label use of the drug?
MR. DIAMANTATOS: Objection. Form. Vague.
THE WITNESS: I have to be -- I'm being careful, because if it's prescribed, that's -- that's between a physician and a patient.
BY MR. CRAWFORD:
Q. Right. I understand what you're saying.
So doctors can make the choice to -- they're not breaking any law by prescribing it off label for a use that's not in the approved indications, right?

Page 117

A. That's correct.
Q. It's just that the company can't market it to the doctors for an off-label use; that's the rule, right?
A. That's correct.
Q. And so for Actiq, it's approved, in part, to treat breakthrough pain in patients with cancer, right?
A. Who are non -- who are opioid tolerant, yes.
Q. Right. Who are opioid tolerant.
So one of the -- so if somebody without cancer uses the drug or is prescribed the drug, it might be legal for the doctor to do that, but it is an off-label use? That would be --
A. Correct.
Q. -- one off-label use, correct?
And somebody who wasn't opioid tolerant, meaning they hadn't used opioids before, that would be an off-label use, right?

A. That's my understanding.
Q. And if it was used for something other than breakthrough pain, which is in the indication, then that would, again, be an off-label use?
A. That's my understanding.
Q. On Page -- let's see, the bottom of Page 22, there's a direct patient feedback section component, chain pharmacy callback system. Top of Page 23, it says, A callback system will be used to directly query Actiq patients.
And, you know, one of the queries was whether the patient received an Actiq welcome kit.
Do you see that at the top bullet point?
A. Yes.
Q. And then it says, The partners included in this system include Rite Aid, Eckerd, Walgreens and the Merck Medco system, right?
A. That's what it says.
Q. So this program, or callback

system, under the RiskMAP, was to be run through those five partners, right?
A. That's what it says here.
Q. Right. And then the next section, 8.2, IMS Component.
It says here that, Prescription data will be routinely monitored. The source of these data will be IMS Xponent, the largest sample available of Actiq prescriptions, segmented by physician specialty, to determine prescribing needs. The IMS Xponent data sample represents prescriptions from over 1 million prescribers and over 35,000 retail pharmacies. Additionally, IMS Xponent captures 60 million mail order prescriptions per year.
These data provide the prescriber's name, the physician specialty and zip code. These data will be analyzed by comparing the proportion of prescriptions written by specialties such as hematologists/oncologists

(appropriate patient selection) to usage by specialties such as surgeons, (inappropriate patient selection).
So based on this, your understanding was, the RiskMAP required use of this IMS Xponent database to analyze the prescribing of the doctors of Actiq, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
Go ahead.
THE WITNESS: That's what it says here, yes.
BY MR. CRAWFORD:
Q. But it's your understanding, too?
I mean, I know it says that, but the company -- the RiskMAP is something that the FDA -- or that was required as a condition or part of the approval, right?
A. That's correct.
Q. And to make changes, you had to get -- submit a supplement, and the

FDA had to approve any change to this RiskMAP, correct?
A. That's correct.
Q. Let's go to the next page, 24, Wholesaler data.
It does say, Cephalon, Inc. will receive information on retail pharmacy sales. Additionally, every two months -- skipping down to the third paragraph there -- Additionally, every two months a Cephalon Inc. trade sales specialist (wholesaler representative) will call on the high-volume Actiq wholesalers. This person will request information on any additional pharmacies which need to be added to the list. Information from Cephalon's -- from Cephalon's meetings with wholesalers will be shared with the oncology sales specialists for follow up. The sponsor will monitor for compliance at the RMP point of dispensing and report violations to the FDA quarterly, along with any interventions made as a result.

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So do you recall if Cephalon had this wholesaler data process in place, reporting process, during the time you were there?

MR. DIAMANTATOS: Objection. Form. Foundation.

THE WITNESS: I believe we did.

My hesitancy is because it evolved. Things were evolving depending upon the year and what was available.

So you'd have to look at the RiskMAP quarterlies all the way along, how things may have changed. So that's why I'm implying that, in general, this is my understanding, but things could -- and operationally things could have changed.

The intention was there, and we did -- we did agree to it. And we did implement it. But it may not be exactly like that, as it

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evolved.

BY MR. CRAWFORD:

Q. Just kind of in your own words, what's your understanding of what the company was to do with regard to this wholesaler data tool here?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: Just what it says, the sponsor will monitor the compliance, and report violations to the FDA quarterly.

And I believe that in our quarterly reports, we explained what we did. So we can find those documents to accompany this.

BY MR. CRAWFORD:

Q. But they were supposed to kind of do some digging downstream, you know; basically the company sold to wholesalers, pretty much, right, the drug?

They couldn't sell it directly to pharmacies, could they?

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A. You know, I don't know, to be honest. It wasn't -- I just don't remember, and I don't know how that worked.

Q. I'll represent, I believe, that the restriction -- there was a restriction, you couldn't sell directly to pharmacies the Actiq.

But, regardless, my question is, this requirement required the company to kind of look downstream at the wholesalers' customers and do some digging about where there might be some inappropriate distribution of the drug?

A. That was --

MR. DIAMANTATOS: Objection. Form. Foundation.

Go ahead.

THE WITNESS: That's the requirement of this. I just don't remember how it was implemented. And the reports would tell you that. So that's why I'm hesitant.

BY MR. CRAWFORD:

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Q. Got it. I understand. Thank you.

Go to 27, Page 27, under 9.1.2, under the section, Groups of Prescribers.

Why don't you take, you know, just a minute or whatever to read this section?

A. Section 9?

Q. Yes. 9.1.2. It's under 9.1, Off-label usage, it's subsection of 9.0, Intervention.

A. Okay. I'm done.

Q. All right. Let me just read this into the record. And I just want to get your understanding, in your own words, of how your department or the company interpreted how this was supposed to be implemented.

It says, If groups of physicians (such as a particular specialty) are identified as having prescribed Actiq inappropriately, and these prescriptions represent potential

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off-label usage greater than 15 percent of total quarterly Actiq prescriptions, Cephalon, Inc. will contact the appropriate professional society (i.e., American College of Surgeons, American Society of Anesthesiologists). This letter will outline prescribing concerns and offer to implement an educational program in conjunction with the professional society in a national setting.

Prescribing patterns will be monitored for the physician groups in question and should the level continue to exceed 15 percent of total Actiq prescriptions for two additional quarters, an aggressive educational campaign will be initiated by mail, clearly warning of the potential liabilities of prescribing Actiq to inappropriate patient populations.

So this was a requirement of the RiskMAP, to have this monitoring of groups of prescribers, right?

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A. That's correct.

Q. And do you recall what department there at Cephalon was in charge of implementing this tool?

MR. DIAMANTATOS: Objection. Form. Foundation. Assumes facts.

BY MR. CRAWFORD:

Q. Or mechanism, I would say?

MR. DIAMANTATOS: Same objections.

THE WITNESS: It may have been from the IMS database.

If I looked at the report, I could tell you better. The report describes how we did everything.

BY MR. CRAWFORD:

Q. But I'm trying to find out what department.

Was sales and marketing the department that collected this information and provided it to you for the quarterly report?

MR. DIAMANTATOS: Objection. Form. Foundation.

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THE WITNESS: I believe so.

But if I could see one of the quarterly reports, I could be more specific.

BY MR. CRAWFORD:

Q. Can you give me some kind of account about how the company interpreted this 15 percent requirement?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Assumes facts.

THE WITNESS: I can tell you exactly if I saw the report.

BY MR. CRAWFORD:

Q. Right.

A. I'm just trying to remember, and I don't want to say the wrong thing.

Q. All right. We'll try to pull a report --

A. That will be helpful.

Q. -- and give that to you. Thank you. Yes.

And then the last page here, 10.0, on Page 29. It does say, Cephalon,

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Inc. will provide a quarterly report to the FDA compiled from all data collected by the methods described under the Actiq surveillance and monitoring program interventions, see Sections 8.0 and 9.0 of the document. This report will describe and provide data and any concerns for child safety, diversion and off-label usage.

So that was -- that's the report that you were required to prepare, right?

A. That's correct.

Q. So one of those components was to provide data and concerns about off-label usage to the FDA, because they wanted to know what was happening, right?

A. Yes.

MR. CRAWFORD: Can we go off the record for a little bit? I think we might have a quarterly report, and this might be a good time to get that.

VIDEO TECHNICIAN: Going off

the record. 11:22 a.m.

- - -

(Whereupon, a brief recess was taken.)

- - -

VIDEO TECHNICIAN: We're back on the record at 11:34 a.m.

- - -

(Whereupon, Teva-Marchione Exhibit-9, TEVA_MDL_A_04578988-9017, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. Ms. Marchione, we did find a quarterly report, I believe, Exhibit-9, dated September 24th, 2003 signed by you. It's TEVA_MDL_A_04578988.

Is this a quarterly report that you referred to earlier?

A. Yes, it is.

Q. And this was prepared or compiled by you or your department, right?

A. That's correct.

Q. And submitted to the FDA, correct?

A. That's correct.

Q. And if you could, maybe take a few moments to look at it, maybe go to the first page, which is at 93.

It says, Actiq risk management program, 17th quarterly report, April 1st, 2003 to June 30th, 2003.

This was the report that was referenced in, I think, Section 10 of the RiskMAP document, right?

A. That's correct.

Q. And this is a report that you would prepare in your ordinary course of business, right?

A. That's correct.

Q. And this one, in fact, was submitted to the FDA?

A. That's correct.

Q. And I think the first page here, Page 2, actually, it says, Actiq

surveillance and monitoring programs, Sections 8 and 9, surveillance goals and activities.

And then it starts with direct patient feedback and continues through with sections that correspond to the actual RiskMAP sections, right?

A. That's correct.

Q. So I think my question was -- that you wanted to refer to it -- I think it was dealing with the 15 percent requirement in the Actiq RiskMAP, right?

A. That's my recollection.

Q. Yeah. I think that was -- just so you can pull it up next to it, that was Exhibit-7, Page 27, groups of prescribers, under off-label usage.

And I think I had asked you exactly how -- how the company interpreted and implemented this mechanism to evaluate the prescribing by these groups of physicians.

Is there anything -- and

take your time, but is there anything in the quarterly report that triggers your recollection of how the company might have interpreted and utilized and implemented that mechanism?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: Just give me a minute, please.

BY MR. CRAWFORD:

Q. Take your time.

This one, actually, I think, at Page 11 and 12, seems to skip over the 9.1.2 section.

A. That's what I'm looking at.

Because we did -- oh, God. We did always have the 15 percent cutoff. There was an IMS printout that listed -- did we -- wait a second.

So in Section 8.2.1 on Page 3, under, NDC Source Prescriber audit, it states there, The data from the NDC Source Prescriber audit shows that none of the nontargeted physician specialties

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exceeded 15 percent of the total prescriptions during 2Q03.

So the actual documentation, if I remember correctly, you know, was very long and -- but we would get the information and review it and put that statement.

So it's on Page 3, under 8.2.1.

Q. Right. Okay. So the corresponding section in the Actiq RiskMAP is on Page 23, under 8.2.1, IMS Xponent. That shows a different data source, NDC Source Prescriber audit.

Is that the reason why that's different than what's required by the RiskMAP?

A. This is one of those evolving operational things. And maybe the IMS Xponent wasn't available any longer. So I think they switched over to an NDC component.

Q. Do you know if the FDA ever approved that switch?

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MR. DIAMANTATOS: Object to form.

Go ahead.

THE WITNESS: I doubt it. Again, we informed them every time we changed something. But, as I mentioned earlier, they -- we never got, you know, an acknowledgment letter.

We definitely sent it in writing that -- what we were changing along the way.

BY MR. CRAWFORD:

Q. Right. But there's nothing in 8.2.1 that talks about the 15 percent --

A. So I think --

Q. -- specialties. That comes under -- if you look under the RiskMAP on Page 27, that 15 percent is under 9.1.2.

And you'll agree with me that that section is omitted, 9.1.2, from the report, right?

A. I agree. And it's one of

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those historical -- if you looked back in the communication logs, we probably communicated that we were now combining -- using the IMS for the Xponent.

And that's why we say here explicitly that the nontargeted physician specialties exceeded 15 percent of the total prescriptions.

And it's one of those things that you have to go back historically and look at all the FDA correspondence to figure out when that changed and why, and we explain that.

Q. But, I mean, it would have been just as easy to put it under 9.1.2 on Page 12, right after 9.1.1, talking about individual prescribers.

I mean, is there a reason why you couldn't have put it under that section, which is the logical section, because that's where 15 percent is discussed, in that section?

A. Right. And I believe -- I

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can't remember exactly, but because they were both kind of looking at the same thing, I think we combined it into that.

So we could repeat it again, but -- if you looked at the progression of the reports and the communication, it would probably make a lot of sense where things were. We told them we were moving things or what we were doing.

So we were probably using the same source now to answer both things. So this came up first, and that's why we put it there.

Q. So was there ever any point in time that you, in one of these reports, reported that there were nontargeted physician specialties that did exceed 15 percent of total prescriptions?

MR. DIAMANTATOS: Objection. Form. Vague as to time.

BY MR. CRAWFORD:

Q. At any time.

A. I think there was one --

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MR. DIAMANTATOS: Same objection.
THE WITNESS: -- quarter, or two. It was later in the -- it was later, you know, towards the end of the marketing or the sales.
So I don't know -- I can't exactly -- but we only exceeded it once or twice. That why I wanted you to actually see this, because we never -- I think we initially -- we can find the date -- we never exceeded it except for once or twice.
BY MR. CRAWFORD:
Q. All right. And then do you remember what nontargeted specialties exceeded 15 percent in those reports?
A. I don't remember.
Q. All right. And what is a nontargeted physician specialty?
A. I believe -- I believe somewhere down the line we communicated to the agency who -- the groups that

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they -- I don't know who, I guess, commercial, identified were not prescribing for oncology.
So it could go beyond oncologists. And so whatever groups that they identified, there's a communication somewhere and why they chose those groups.
Q. All right. So just turn to Page 27 of Exhibit-7.
I'm trying to understand about the -- this is 9.1.2.
A. 27 --
Q. That would be exhibit, I'm sorry, Exhibit-7, which is the Actiq RiskMAP.
A. I'm sorry, what page?
Q. I think you might be in the quarterly report.
A. You want 27, sorry.
Q. Yes.
A. Okay.
Q. And I'm just trying to understand what you're reporting here.

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So what the FDA -- or what the RiskMAP says is, If groups of physicians (such as a particular specialty) are identified as having prescribed Actiq inappropriately and these prescriptions represent potential off-label usage greater than 15 percent of total quarterly Actiq prescriptions, Cephalon will contact the appropriate professional society.
A. Right.
Q. It gives examples, American College of Surgeons, American Society of Anesthesiologists.
And then you say in your report to the FDA, under 8.2.1, Data from the NDC Source Prescriber audit show that none of the nontargeted physician specialties exceeded 15 percent of the total prescriptions during Q203.
So the nontargeted physician specialties are specialties that are not -- would not be prescribing the drug as it was indicated, right?

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A. It's a commercial question. My understanding is that they were -- they wouldn't target prescribers who weren't prescribing to cancer patients.
Q. All right. So none of those specialties exceeded 15 percent of total prescriptions, is what you're saying here?
A. That's correct.
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That's my understanding, yes.
BY MR. CRAWFORD:
Q. Now, what about the targeted physician specialties, what would they be, for example, like, anesthesiologists?
A. It was defined -- somewhere in previous communications we defined that. There's so many, you know -- I'd have to look at all the documents.
Q. Sure. I understand.
Is there, like, an SOP or something that may have helped clarify

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things?
A. I don't know. It would be with the commercial group, because they were giving -- they were doing -- it was a marketing research group that was giving us this IMS data, and they would -- and it may be on file somewhere where they would define, you know, what their search criteria was and what the data were.
Q. All right. So when you did -- when the company did identify some nontargeted specialties that exceeded 15 percent, did they -- are you aware if they took the appropriate steps here to write letters, or if it exceeded two quarters, embark on aggressive educational program?
A. To the best of my recollection, what we did was any time we were aware of off-label prescribing, we sent a letter. It was also a visit by the -- it could have been by the sales rep or MSL.

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And so we did -- rather than going to a group, we wanted specifically to target that physician, to make sure he was aware of the prescribing. So we -- so we did it in that way because it was easier to identify -- we felt it would be more effective to target the actual prescriber than to a general group. So we did send off-label letters.
Q. All right. But that's 9.1.1, that's the individual prescriber and you become aware that they're prescribing off label, the RiskMAP requires a letter sent to the individual prescriber, right?
A. Right.
Q. And that's on Page 27 here of Exhibit-7, correct?
A. Right.
Q. That's that mechanism, right?
A. Right.
Q. But there is an additional mechanism in 9.1.2, would you agree with

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me, that if you're aware of a group of physicians that prescribe Actiq inappropriately and they exceed 15 percent of the total Actiq prescriptions, you're required to write a letter, at least to the professional society, outlining the prescribing concerns and offering to implement educational programs, right?
MR. DIAMANTATOS: Objection. Form. Asked and answered.
THE WITNESS: To that point is, I think -- I can't remember exactly. I think we looked into going to the society, and it was -- we felt that going to the specific doctors who were prescribing off label would be more effective.
I don't know if they -- I'd have to -- I don't remember. I think they did try to go to those societies, and, you know, they felt that that's not the correct

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place for it.
You know, again, this goes back to -- when this RiskMAP was put together, it was done quickly. There was not a lot of research behind it. So there's a lot of things in here that couldn't actually be implemented.
So what we tried to do is -- actually, I'd say, 90 percent of the time we were overly aggressive in going to more specific -- we thought that would be better to go to each physician, as opposed to a group.
But we did research trying to go to those groups, and I don't think we could.
BY MR. CRAWFORD:
Q. So did you do, like, a mass mailing, then, to doctors about -- for Actiq at any time?
I mean, after you discovered -- after you reported that

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there were a group of physicians, did you do a mass mailing to that group of physicians with information about the proper prescription of the drug?
A. There were a couple mass mailings done over the course of commercial -- of commercial. And I can't remember what triggered that.
But that was to -- that was, like, I don't know -- I don't know which groups we chose.
We talked -- I'm trying to remember. We talked about trying to do that. And I don't know if they could get a list or -- it didn't seem as effective. So we went to the most conservative, and went to all the physicians that were prescribing off label, as opposed to -- that's, basically, what I can remember.
We've had meetings on it, and I just don't remember the details.
We tried to comply with every single thing in this document. And when we wouldn't, we went more

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conservatively.
Q. Okay. So let's split up Actiq and Fentora.
For Actiq, was there ever -- you've heard of a Dear Doctor letter, right?
A. Yes.
Q. Is that what you're thinking that was sent out, just a form Dear Doctor letter, with the doctor's name on it, or was it -- were you sending individual letters to doctors who you actually knew were prescribing off label?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: The latter.
BY MR. CRAWFORD:
Q. So you didn't do kind of a general mass mailing to -- when you saw this targeted -- nontargeted specialty that was prescribing it more than 15 percent, you didn't do a mass mailing, not knowing whether they were prescribing off label or on label, that particular

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doctor; you just tried to find doctors who you thought were prescribing off label?
MR. DIAMANTATOS: Objection. Form. Mischaracterizes testimony.
THE WITNESS: We tried to do that. Somewhere there's a memo to the file.
We tried to do everything that was in there, and we couldn't for some reason. And it's documented. Whether the society wouldn't accept something like that or wouldn't give us the names or -- there were reasons.
But I just -- I can't remember offhand.
BY MR. CRAWFORD:
Q. But if you sent letters to the FDA -- or to these doctors, it would be reflected in one of your quarterly reports to the FDA, right?
A. It is. We talk about how many letters went out that quarter.

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There was a number --
Q. Are you looking for a section that -- where you list the doctors or give an account of the individual letters that were sent out to doctors?
A. Yes. Do you see that?
Q. I recall seeing something like that in others letters. Maybe it's not here.
But so the practice would have been, if you did send out letters under 9.2.1 or 9.2.2 or 9.1.2, you would report that to the FDA in one of the quarterly reports, right?
A. That's my recollection.
Q. And you would not -- your practice was not to send those letters out and then not tell the FDA you did it, once you found one of these triggers?
A. I thought, on a quarterly basis, we told how many letters went.
Q. I'm just trying to -- if I were trying to figure out what was sent

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out to doctors that you referenced, I could reference your quarterly reports to get an accounting of what was sent out, right?
A. That was my recollection, yes.
Q. And that was your practice to do that?
A. Yes. It went --
Q. That's all I really want to know. Because I don't have all the reports with me --
A. I understand.
Q. -- but I want to make sure that if I want to try to find out what was sent out --
A. Yes.
Q. -- the best source is for me to go back over your quarterly reports and look to see what was sent out, right?
A. And if it wasn't in the quarterly report, we had a file where we kept -- I don't remember, but we kept all, like, any memos, if something

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unusual would happen or whatever, we would always ask for a memo to file.
And, like, our safety group had all the -- each department would keep their own files of what they sent.
So -- but there was -- I remember there being a RiskMAP file that we kept, I guess, in the document control room that had all the memos and anything unusual that happened.
Q. Right. But the letter, the FDA wanted to know, one, if there was a problem, which you identified with the 15 percent threshold being reached, and then what you did about it?
A. Right, right.
Q. So the practice would have been to include it in the quarterly report to the FDA, say, hey, listen, we saw a specialty exceeding 15 percent and we sent a letter out to individual doctors, and you either gave them the number or the names or whatever, right?
A. One or two of the quarterly

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reports reflect that one group only went over 15 percent and what we did.
Q. Right.
A. I can't remember.
But, I guess, I was -- I remember explicitly that it was only that time that it ever reached over -- that only the one group reached over 15 percent.
Q. And you recollect that the report, you reported what you did in response?
A. Yes.
Q. So that would be the best way for me to find out what letter --
A. Exactly.
Q. -- or if anything went out?
A. And maybe in one of the reports where it hit over 15 percent.
But, again, there were so many of them and --
Q. So many reports?
A. Yes.
Q. Yeah. So we'll go back and

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look for that.
A. Right.
Q. We don't do it today.
A. But it was very -- I mean, it only hit it once or twice.
Q. All right. What about targeted groups? What about if a targeted group exceeded 15 percent and you determined that potentially over 15 percent -- or potentially that the off-label prescribing within that targeted group exceeded 15 percent of total Actiq prescriptions, would that be something that you would monitor and report to the FDA?
A. I don't think that was -- I don't think that was one of the requirements for the RiskMAP, because the targeted were patients -- were people who were supposed to be prescribing, right?
But any time -- in general, any time we ever became aware, through, like, a serious adverse event -- any time we became aware of an off-label use, we

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would send a letter, whatever -- whatever mechanism we heard about it.
Q. You mean to an individual doctor?
A. Yes.
Q. Right. But I'm talking about the groups of physicians requirement, 9.1.2.
If you look at the RiskMAP on Page 27, it doesn't talk about targeted or nontargeted doctors --
A. Right.
Q. -- you're basically saying that you did not have to monitor the off-label usage for specialties that were targeted, right?
A. That's correct. That's not required.
But we did -- because it's a redundant document, we did, regardless if they were in the target or nontarget, if we became aware of an off-label use, then we would send a letter.
So this is just saying

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that -- this is saying that you're allowed to go to targeted, because that's the people prescribing for oncology.
Q. Right.
A. So that's fine.
But the FDA, the intention of this was to look at the nontargeted group, and if they were prescribing over 15 percent, that's when the FDA became concerned.
Q. What about -- what if a targeted group, say -- I mean, targeted groups, as far as I understand -- that Cephalon designated as target groups were not only oncologists, but they also designated anesthesiologists --
A. Right.
Q. -- as a targeted group, right?
A. Right.
Q. So that meant that Cephalon felt it could legitimately detail and promote to those -- to that group, right?
MR. DIAMANTATOS: Objection

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to form.
THE WITNESS: That's correct.
BY MR. CRAWFORD:
Q. So what if a group of anesthesiologists, what if you look at that targeted group, and you look at -- you determined that over 15 percent -- the prescriptions from that group potentially exceeded 15 percent of all total Actiq prescriptions that were off label, wouldn't you have to take the corrective action under 9.1.2 to inform the professional societies and offer up these educational programs?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: So --
BY MR. CRAWFORD:
Q. Under the RiskMAP?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I'm not the right person to answer this.

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But there's an IMS ability of seeing, like, what each -- I don't think they could find that out. I think that's why it was written this way.
So they could see what groups were prescribing, and when they could infer it was off label because it was not targeted.
But I don't think they could -- at least back then, I don't think they could tell, like, if that psychiatrist was prescribing on label, off label. Because I think that's a HIPAA thing, or whatever.
BY MR. CRAWFORD:
Q. I see what you mean.
So you're basically saying that for the, quote, targeted -- look at 9.1.2 on 27.
They don't talk about targeted or nontargeted doctors, right? That's a Cephalon interpretation, or how

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they implemented this provision, right?
A. Right.
Q. But it does talk about if it exceeds 15 percent --
A. Right.
Q. -- to inform professional societies, right?
A. Right.
Q. And one of the societies is the American Society of Anesthesiologists, right?
So if Cephalon thought that anesthesiologists were a targeted group and didn't have to look at whether they were prescribing it off label within that group, then why is the FDA saying that if that group exceeds 15 percent, that they need to go to them and educate them?
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. I don't understand that.
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.

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BY MR. CRAWFORD:
Q. Can you please explain that to the jury?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.
THE WITNESS: I think I explained it as best I could.
BY MR. CRAWFORD:
Q. All right. So it's also your testimony that if it was a targeted group, say anesthesiologists or oncologists, that IMS didn't have a way to find out exactly whether, within that targeted group, they were prescribing it off label or not?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Mischaracterizes the witness's testimony.
THE WITNESS: I just don't know IMS -- you know, you'd have to ask somebody who specializes in that.

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That was my understanding.
BY MR. CRAWFORD:
Q. Okay. Sure.
And that -- you get your information from other people in the company, you didn't know directly, right?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. Is that correct?
A. In that particular area, yes.
Q. And would that have come from sales and marketing, that information about breaking out specialties and whether they did off label --
A. It was marketing -- it was marketing research.
Q. Thank you.
THE WITNESS: Are we done with these?
MR. CRAWFORD: Yes. We might refer back later, so go

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ahead and stick them face down.
We marked next here a document entitled, Quality Assurance Memorandum to QA File, from David Brennan, subject, Internal audit of Actiq risk management program, second quarter 2003. It copies Tim Sheehan, Carol Marchione, Bob Bader and Mark Solomon. It is marked confidential, D0324.
- - -
(Whereupon, Teva-Marchione Exhibit-10, No Bates, Quality Assurance Memorandum, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. Do you recall seeing an audit report before by Mr. Brennan?
A. Yes.
Q. And this is dated, it looks like it's handwritten, December 2nd, 2003.

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And you're a recipient, right?
A. That's correct.
Q. And Mr. Brennan was in the quality assurance department?
A. That's correct.
Q. And he -- is it your understanding that he was doing some kind of compliance audit to see whether the company was complying with the Actiq risk management program, right?
A. That's my recollection.
Q. And he has here kind of a summary -- executive summary here. And he lists as his objective, Audit Actiq risk management program reporting activities to determine compliance with filing commitments, right?
A. Yes, that's correct.
Q. And then his conclusion is, Based on the findings of this audit of 12th through 15th quarterly reports, Cephalon is not in compliance with the commitments communicated in the risk

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management program dated August 1, 2001 filed with Actiq NDA Number 20-747.
The identified issues will be communicated to regulatory affairs management -- that would be you, correct?
A. Or my manager.
Q. Okay. And who was that?
A. The date -- do we know what date this is?
Q. December of '03.
A. It could have been Ken White at the time. I'm not quite sure.
Q. Was he an interim manager before -- while that seat was vacant that we looked back at the --
A. He was the initial manager. I just don't remember when he left.
Q. All right. But I think if you look back at Exhibit-3 --
A. It was vacant?
Q. Yes.
It says, May 28th, 2003, that that position was vacant above you.
So would it have been an

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interim person, or by then did Mr. Raczkowski come into place?
A. I think by then it was maybe the chief medical officer, Paul Blake.
Q. Paul Blake then.
He was there on an interim basis, right, until they could find a full-time regular position?
A. He was the -- he oversaw my level above, so yes.
Q. All right. So -- but that position was vacant, at the time, right above you still?
A. I believe so.
Q. So Mr. Raczkowski was not involved at the time this report was prepared?
A. I believe so.
MR. DIAMANTATOS: Object to form.
MR. CRAWFORD: Is the form I mispronounced his name, maybe?
BY MR. CRAWFORD:
Q. So do you recall receiving

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this memo?
A. Vaguely.
Q. And he does go through the audit results, starting on Page 2.
I just want to kind of go through a couple of them here and see if you remember these.
A. Under 8.1, about midway through, 8.1.1.4A, Rite Aid, Eckerd, Walgreens, Merck Medco, participating chains are not identified in the report. Walgreens is the only chain represented. The RiskMAP process guide indicates CVS ProCare data is included, too, but this does not match current practice. The paragraph of the RiskMAP indicates that this program will only be conducted for the first year of sales. It also indicates that after one year, the company will negotiate with FDA to discontinue the patient survey.
Do you know whether the company ever negotiated to discontinue the patient survey?

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MR. DIAMANTATOS: Objection. Form. Foundation. Assumes facts.
THE WITNESS: I don't remember. But that could have been one of the many communications to the FDA of something we were changing.
BY MR. CRAWFORD:
Q. Do you recall if the FDA ever signed off on dropping that program?
MR. DIAMANTATOS: Objection. Form. Assumes facts.
BY MR. CRAWFORD:
Q. Or negotiated a different program there?
MR. DIAMANTATOS: Objection. Form. Foundation. Assumes facts.
THE WITNESS: As I mentioned previously, we -- it seemed like the communication was more one-sided. So we didn't hear back.
BY MR. CRAWFORD:
Q. Right. But there was no

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official approval by the FDA of the change?
MR. DIAMANTATOS: Objection. Form. Assumes facts. Foundation.
THE WITNESS: No.
BY MR. CRAWFORD:
Q. Okay. In fact, was the company only using Walgreens data at the time?
MR. DIAMANTATOS: Objection. Foundation.
THE WITNESS: I don't remember.
I do remember that throughout this there were probably a lot of things that -- going back to things were different. And if he was looking at the original, because it wasn't updated, we couldn't actually do a lot of the things that were required.
So that's why they're just using Walgreens. Because some of

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these things just weren't able to be done.
BY MR. CRAWFORD:
Q. Do you know if the company ever submitted a supplement to try to change the provision to narrow it down to Walgreens?
A. I believe -- I believe we did. Every time we tried to -- you know, we came across something that was different, we communicated it at some point.
I'd have to look -- it was so long ago. I would have to look.
Q. Well, I mean, before this point in time, did the company ever submit some kind of formal application to change the process to narrow the number of partners here that were doing this?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: You know, if I -- I'm trying to remember -- of having a phone contact with the

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FDA and saying, you know, we've communicated -- and I believe what the project manager told us, well, communicate -- just communicate it and acknowledge it and -- until you would get an approval.
So it would have to be in my communication logs. We could -- obviously, I was concerned that we weren't getting feedback. And I think that it was communicated that she told me to acknowledge it in writing and then just keep going until you change it.
I can't say for sure. But that's a recollection I have, because I was concerned that we needed to change certain things.
BY MR. CRAWFORD:
Q. But the FDA -- the RiskMAP requires a supplement, which is a formal application, to make a change, correct?
MR. DIAMANTATOS: Objection. Form. Foundation.

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THE WITNESS: We tried that. I mentioned that, yes.
BY MR. CRAWFORD:
Q. Right. But I'm just asking, did you try, after this audit, to do that or before this audit to make the change?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered.
THE WITNESS: I'd have to look at the log. I just don't remember.
There was a lot of communication about changes.
BY MR. CRAWFORD:
Q. All right. Then 8.2.1, it says that, NDC source prescribers was used instead of IMS Xponent. NDC source prescriber data is not reported. We only report that no specialty exceeds 15 percent.
That was -- that was what we looked at when you flagged it under 8.2.1, right?

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A. That's correct.
Q. Then -- I mean, just looking through this, he found -- Mr. Brennan did find a number of inconsistencies between the practices of the company in effectuating the RiskMAP and what the RiskMAP required, right?
MR. DIAMANTATOS: Objection to form. Foundation.
THE WITNESS: So what I explained before is there were inconsistencies against the original one that he looked at.
If he -- I used to head up the compliance group. If he did his -- if it was correctly evaluated, he -- what should have happened is he would have gone to look at the actual documentation, which was -- which I saw originally, and it was stored in files. And he could have looked for himself about the 15 percent, as an example.

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So there is documentation to support all this. I don't think in this -- in this audit report it was evaluated as appropriately as -- maybe as deep as it should have been.
Because we have documentation -- just like he could have -- he could have referenced the documentation where we communicated to the FDA what our changes were.
That gives you a sense that -- I think this was a first pass, and this should have been a deeper dive, in terms of some of these findings, because there -- there were -- and we actually -- we had follow-up to this case.
But there was everything, you know, that we were doing correctly. And we had documentation to support it.
BY MR. CRAWFORD:

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Q. But the RiskMAP requires actual approval by the FDA, through a supplemental process, to make changes; that's mandatory in the RiskMAP, right?
MR. DIAMANTATOS: Objection. Form. Asked and answered.
THE WITNESS: I mean, I don't know how many times you want me to say it.
We did -- we communicated one way. I talked to the FDA project manager. And we had to -- some of these things couldn't feasibly be done, and so what are we supposed to do?
You know, if anything, we went -- for instance, there's questions in the RiskMAP that you were supposed to ask on callback.
By the time we kept evolving and making this more and more robust, we had pages of questions to ask. So, if anything, if you saw what we really did, it was a

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lot more robust than the initial RiskMAP.

We added a whole lot of things, but we couldn't get it included. Not only couldn't we get the changes, but we could not get the additional things we added.

So, you know, and -- eventually the FDA, we had a meeting with the FDA, we made them aware of everything. We reviewed all the data with them. They had no problem with what we were doing.

BY MR. CRAWFORD:

Q. Okay. They had no problem with any of the practices that you were -- you had in place --

A. That's correct.

Q. Hold on.

-- the practices that you had in place that didn't conform to the exact terms of the written RiskMAP?

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MR. DIAMANTATOS: Objection. Form.

BY MR. CRAWFORD:

Q. Is that what you're saying?

A. Yes. We met with them and we went through the whole RiskMAP process, all the data. And we were -- there were no issues. We never got any problem -- any letters.

And we had, I don't know, 15 people at the FDA in that room who did not have a problem with anything we did. They understood what we were talking about.

Q. And when was that meeting?

A. I remember it was July. I'd have to look at the date.

Q. July of '04, after this report?

A. I'm sorry, I'd have to look at the date. But it was -- there's a big binder -- because we went -- we had a huge meeting with the agency.

It was -- yeah. I'd have to look at the date.

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Q. Let's mark something here.

MR. CRAWFORD: 1138. Let's see if this is the binder or information that you're referencing.

This is July 12th, 2004.

THE WITNESS: That sounds right.

MR. CRAWFORD: We'll give you a copy.

THE WITNESS: That sounds right.

MR. CRAWFORD: Why don't we mark it, and you can just confirm this is the meeting where they said everything was okay.

THE WITNESS: I don't want to say -- let me be clear. I didn't say they said everything was okay. We -- I'm sorry if I misrepresented.

We presented all the information. They received all

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the documentation. And at the end of that, we've never -- they thanked us for coming, and we never received any negative letter or anything to the fact.

- - -

(Whereupon, Teva-Marchione Exhibit-11, TEVA_MDL_A_01575289-972, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. So we marked here Exhibit-11.

And this is the meeting that you're referring to that was to occur on July 14th, right, 2004?

A. July -- that's correct.

Q. We'll get back to this. I just wanted to get our timeline straight.

So Mr. Brennan lists here -- let's go to the items requiring follow up, which is on Page 330 here.

He's listed 14 points,

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right, on those two pages?
A. Okay. Yep. Yep.
Q. So one item requiring follow-up, he does reference the four listed pharmacy chains are not included as required by Section 8.1.1.
Section 8.0 further commits that if any of the four organizations aren't able to participate, Cephalon will substitute another supplier, only Walgreens is represented.
Does that -- does that accurately reflect what the situation was at that time, that only Walgreens was represented?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: Yeah, I'd have to look. I don't know.
BY MR. CRAWFORD:
Q. There are a number of points here.
Number 3, NDC Source

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Prescriber is used in place of IMS Xponent specified in Section 8.2.1.
That's another issue he raised, correct? I think you address that.
A. It's written here.
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. Going to Number 12, he says, The quarterly RiskMAP or RMP report omits Section 9.1.2.
We saw that in Exhibit-9 that we looked at, right?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. Remember 9.1.2 was missing, right?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Right. But we told you that instead we had it addressed earlier.

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BY MR. CRAWFORD:
Q. It says, This section requires that inappropriate prescriptions representing potential off-label usage greater than 15 percent of the total Actiq prescriptions will prompt Cephalon to offer educational programs to the various professional societies. It is further specified -- it further specifies that if the potential off-label usage greater than 15 percent continues for two additional quarters, Cephalon will initiate an, quote, aggressive, unquote, education campaign. No documentation of intervention could be found.
So that was one of Mr. Brennan's findings in this document, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
Go ahead.
THE WITNESS: The reason I'm hesitating is because I'm not sure

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if any did exceed it.
So he's saying -- and that's why I'm reading 13.
BY MR. CRAWFORD:
Q. All right. Yes, let's read 13.
SOP 0426-J02 indicates that only individual specialties with prescription rates exceeding 15 percent of the total Actiq prescriptions will be reported to regulatory affairs. There are approximately 85 specialties reported, three of which are included in the list of exemptions in the SOP. This does not comply with the requirement in Section 9.1.2 that prescriptions representing potential off-label usage greater than 15 percent prompts action.
A. That doesn't make any sense to me. Because it doesn't -- it doesn't talk about exceeding the 15 percent.
I don't understand.
Q. Right. But let's at least break down what he's saying.

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He says there are approximately 85 specialties reported.
So were there about 85 specialties that the practice groups were broken into for evaluation of the 15 percent threshold?
MR. DIAMANTATOS: Objection. Form. Foundation.
BY MR. CRAWFORD:
Q. Does that refresh your recollection?
A. I don't even understand what he's saying.
MR. DIAMANTATOS: Objection to form. One second. One second.
THE WITNESS: Sorry.
MR. DIAMANTATOS: Objection. Form. Foundation. The witness never said she can't remember.
BY MR. CRAWFORD:
Q. Do you remember there was a process, I think you referenced a document that you would get, where they broke down the specialties in order to

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assess if any exceeded 15 percent for nontargeted, right?
A. That's correct.
Q. Okay. And there were, what, approximately three targeted specialties -- or how many targeted specialties were there?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I don't -- I can't tell from -- this doesn't make sense to me, what he wrote. So I can't tell you what he's trying to say.
BY MR. CRAWFORD:
Q. Were there -- is he right that there were approximately 85 specialties that it was broken down to for the evaluation of the 15 percent?
A. I just don't remember.
Q. All right. It says, Action: RA -- that's regulatory affairs, right -- will issue a response audit report by 12/31, right?

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That's the handwritten part at the bottom of Page 331.
A. That's what it says there.
Q. And RA, you would assume that's regulatory affairs, right?
A. But I don't know whose handwriting this is, and, you know.
Q. Do you recall your department preparing a report, or being asked to, about this time?
A. I recall having a meeting to discuss these issues. And I'm sure -- I think there was a document to address all the issues. And it's probably in that RMP file I was telling you.
Q. If you could look at Page 345, there appears to be some type of policy, POL-0009. It's marked draft.
Is this -- can you tell me -- have you seen this document before, and can you tell me what it is?
A. 345.
So my recollection is it's a draft SOP on the RiskMAP.

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Q. Do you recall if there was a final one at this time, or just the draft that he attaches here?
A. I don't recall.
Q. If you turn to the third page of it, Surveillance. Well, actually, go to Section 5, Responsibilities.
It says, The RMP team includes management representatives from marketing, sales, drug safety and regulatory affairs. This team -- or the team ensures that adequate systems are in place to support the RMP program.
And then skipping down, it says, Specific areas of responsibility directly relevant to the various RMP sections are assigned below.
Was that -- even though it says draft, was that kind of the practice at the time with regard to the responsibilities for implementing the program?
MR. DIAMANTATOS: Objection.

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Form.
THE WITNESS: That's correct. Because what the activities were fell under the operations of different groups.
BY MR. CRAWFORD:
Q. Right. And is it accurate that marketing, sales, drug safety and regulatory affairs all had a hand in responsibility for making sure this program was put into effect?
A. To my recollection.
Q. And you're regulatory affairs.
You were one of several departments, right?
A. That's correct.
Q. And then below, it looks like how they kind of divided up responsibility.
If you could look at 5.1 and those assignments, does that basically comport to your recollection of how the duties were divided up -- or

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responsibility was divided up with regard to the RiskMAP?
A. There was a -- there's probably another subsection of marketing research, because a lot of the things came from them, like the IMS database.
So I guess it is subsumed under the marketing group.
Q. So wouldn't marketing research -- weren't they a subset or subdepartment of the marketing department?
A. Yeah. But it's -- yes. Yes.
Q. So it looks like here, at least for your responsibilities, they were, the patient leaflet and package insert, right?
A. That's correct. That's what it says here.
Q. And then the -- skipping down, the FDA quarterly reporting, right?
A. That's correct.
Q. And then things like

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off-label usage, that was drug safety and marketing, right?
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. That had that responsibility?
That was right under 5.4, the second one.
A. Right. Yes.
Q. And then right below that, marketing had the responsibility for the IMS Xponent, IMS NDTI, and promotional message audit, right?
A. That's what -- yes.
Q. And quality assurance had the DEA communications, right?
A. Correct.
Q. And then drug safety, the abuse and other matters, too, right, listed there?
A. That's correct.
Q. Sales and marketing, it looks like they had the responsibility

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for target audience, sales representative training and field direction, right?
A. Again, this is a draft document. I don't know if it's evolved. And we had other groups.
But that's what it says in this document, yes.
Q. But this is, if Mr. Brennan attached it, this must -- do you agree this was the practice at the time, as far as dividing up responsibility?
MR. DIAMANTATOS: Objection. Calls for speculation.
THE WITNESS: Without having an approved document, I'm just hesitant, because if somebody would disagree that that's their area, I can't tell you that.
So if somebody drafts something, people may not agree to it. So you have it in front of you, but it may not be accurate.
It seems correct to me, but I'm sure somebody could have a

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difference of opinion.
BY MR. CRAWFORD:
Q. Fair enough.
So it does say below that, POL-0009, draft, it says, Change, new policy.
So it looks like it's something that people were trying to get down in writing at the time, right?
MR. DIAMANTATOS: Objection to form. Calls for speculation.
THE WITNESS: That's my recollection.
BY MR. CRAWFORD:
Q. But you -- putting the report together, you needed to get input from all these different departments about their responsibility so you could report it accurately to the FDA, right?
A. That's correct.
Q. And I'm just asking for your understanding, not what other people may have thought was their responsibility.
Your understanding was this

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is how the responsibilities broke down and who would report to you on each one, right?
A. What I can remember.
Q. Thank you.
MR. JENSEN: Exhibit-12.
- - -
(Whereupon, Teva-Marchione Exhibit-12, TEVA_MDL_A_011595-553, was marked for identification.)
- - -
MR. CRAWFORD: That's Document 554.
BY MR. CRAWFORD:
Q. All right. We've marked here TEVA_MDL_A_011595, a memo from you, Carol Marchione, to certain people, Paul Blake.
Who -- was he your boss at the time?
A. I believe, because Victor must have been on board by that time, so he was my boss's boss.
Q. I see. Victor Raczkowski,

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who was on the org chart we looked at, right?
A. That's correct.
Q. And then there are other people here from sales and marketing.
Andy Pyfer is one of the recipients, was he in marketing?
A. Yes, yes.
Q. And then a cc to David Brennan, right? He's the guy that prepared the audit?
A. That's correct.
Q. It's dated December 15th, 2003, Re: Actions to respond to audit findings regarding the Actiq risk management program, quality assurance memorandum, 12/2/03.
Do you recall receiving -- or preparing this memo?
A. No. No, actually, I don't.
Q. And if you look at the next page, it looks like these are the 14 points that Mr. Brennan had raised in his audit report.

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Do those look familiar? And then at least some kind of response, right, by the company?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I'd have to review it. It doesn't -- it does not look familiar to me.
It seems that way.
BY MR. CRAWFORD:
Q. Okay. Take a look at Exhibit --
MR. CRAWFORD: Was it 10?
MR. JENSEN: Yes, 10.
BY MR. CRAWFORD:
Q. Take a look at Exhibit-10.
A. Exhibit-10.
Q. Yes. Take a look at Exhibit-10.
It attached 14 points --
A. I'm sorry, what's Exhibit-10? Is that the --
Q. The Brennan report.
A. Okay.

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Q. Those are the same 14 points that he had put in his audit report of 12/2/03, right?
And then this is at least some type of response to each point below it, right?
A. It appears that way.
Q. And, I mean, do you recall anything about putting this memo together?
And take some time to look at it if you want to.
A. Actually, I don't. It could have been initially put together by Tracie Parker, who worked for me.
So is there a particular -- what do you want me to read? Is there --
Q. Yes. Okay. I'll direct you in a second here.
But this would have been -- if somebody prepared something for your signature, you would have read it?
A. Definitely.
Q. Definitely, okay.

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So when you're on -- you have no reason to doubt that this isn't a record from -- from the -- from your regulatory files, right?
A. That's correct.
Q. Okay. And you would have -- if somebody else helped prepare it for you, you would have read it and verified that you agreed with it, right?
A. That's correct.
Q. So I just want to direct your attention here, I guess, to the comments on the first page.
The memo states, In response to the audit findings outlined in the quality assurance memorandum regarding the Actiq risk management program, RMP, representatives from quality assurance, global product safety, marketing, legal, and regulatory affairs met on December 11th to review the 14 items requiring follow up.
Do you see that?
A. Yes.

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Q. Do you recall that meeting at all? Is that refreshing your recollection?
A. I believe there was a meeting to talk about this afterwards, I do.
Q. It says, Additionally, a meeting with sales and marketing needs to be convened to discuss their understanding of the, quote, inappropriate, unquote, physician specialties to be monitored for the 15 percent limit, Items 12 and 13. Due to the additional activity, it was estimated that a memo to respond to the audit finding would be issued by year end.
Subsequently a revised RMP containing any necessary revisions will be issued by the end of January 2004 for review by the management of the various departments impacted by the RMP.
So do you interpret the intent here as to looking at Mr. Brennan's points and providing a revised

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RMP based on the points that he had raised?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: That's how I would interpret this.
BY MR. CRAWFORD:
Q. And do you know if, in fact, a revised RMP was prepared subsequent to this memo, for the Actiq risk management program?
A. I can't remember. But it would be in our log.
Q. Do you recall, you, yourself, putting one together, a revised RMP?
A. I have hundreds of submissions that I put together. So, I'm sorry, I'd have to look at the log.
Q. Understood. Thank you. All right.
It says, below that, Post -- updated, post-meeting note: Legal (Ed Berg) met with sales following the 12/11

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meeting and determined that the required concepts of Number 9 are being met through a regular sales department process. And, further, that Item 13 is adequately outlined in SOP 0426-J02. This information will be reflected in the year-end memorandum noted.

So, basically, the determination was made with these groups that met, which included all these groups, that the existing SOP adequately addressed the 15 percent issue, right?

A. I mean, that's what it says here.

At this point, I think, following this audit, our legal group took over kind of the oversight, more than myself, of everything coming from our sales and marketing. And that's Ed Berg's reference. So, I mean, that's what this is saying.

Q. All right. But it's also saying that the SOP, in their view, looked adequate to address the issue?

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A. That's -- what you read is what it says.

Q. Take a look at Number 13. Actually, it does say, We respectively request to defer our response to this follow-up item. An internal meeting should be convened to discuss how the pain specialists are determined.

So at this point, at least, there was no official response to the 13 -- it looks like there was going to be a follow-up discussion about it, right?

A. What I mentioned to you is then, from that point, our legal representatives took over that point and that process.

So I think I was out of the loop at that point. So that's -- that's as far as I could respond to it.

Q. And that was Mr. Berg, then, right?

A. It was, yes.

Q. And he was in the legal department?

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A. Yes, he was.

Q. It looks like Mr. Berg has some other responsibilities with regard to these points, including Point 10, it looks like somebody wrote, Ed Berg?

A. Yeah, that's not my document.

Q. That's not your handwriting here?

A. No.

Q. Let's go to --

MR. CRAWFORD: How we doing? Do you want to keep going here or take a short break for lunch? How do you feel?

MR. DIAMANTATOS: Why don't we take a lunch break?

THE WITNESS: Yes, let's take a lunch break.

VIDEO TECHNICIAN: Going off the record at 12:39 p.m.

- - -

(Whereupon, a luncheon recess was taken.)

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- - -

VIDEO TECHNICIAN: Back on the record at 1:13 p.m.

BY MR. CRAWFORD:

Q. We have since, during the lunch break, retrieved a document that appears to be the 1999 RiskMAP, which we had referenced earlier.

I think that -- we were looking at Exhibit-7, which is the August 1st, 2001 RiskMAP listing Anesta Corp, a subsidiary of Cephalon. And I think we've been operating off of that.

But you thought that possibly, I think, correct me if I'm wrong, that there was an earlier RiskMAP that may have been the actual operative one from '99.

And so we've attached Exhibit-8, kind of a large, full document, but with a copy of a Page 7857. This is document TEVA_MDL_A_08387849. At Page 7857 is what appears to be a February 9th, 1999 RiskMAP.

- - -

(Whereupon, Teva-Marchione Exhibit-8, TEVA_MDL_A_08387849-8059, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. And I just want to ask you if this refreshes your recollection that that's the '99 RiskMAP that you were thinking of?

A. It may be. I'd have to look word by word. I didn't submit this.

And I don't know if there was FDA changes to it. So I really can't say for sure.

Q. Yeah. But you had thought, possibly, that the effective one that ran through all the time you were there was the '99 RiskMAP, not the '01, which you thought may have had some adjustments to it that hadn't been approved by the FDA; is that correct?

MR. DIAMANTATOS: Objection.

Form.

Go ahead.

THE WITNESS: So the way it works is they submit it -- you'd have to see the correspondence back-and-forth with the FDA.

Because I was thinking about looking at the approval letter, because sometimes they'll reference the date of the submission for the RiskMAP.

BY MR. CRAWFORD:

Q. Who is "they"?

A. FDA.

So this is considered -- until I know that FDA said, this is approved, this is just a draft, basically.

Q. Right.

A. So I don't know if the approval letter referenced this as the RiskMAP or if there was correspondence in between.

You know, anything to the

NDA is dynamic, so it's not -- it's a living document. So there's nothing that's necessarily in time, unless it says it's approved.

So the FDA said -- if in the approval letter it says, your RiskMAP as of February 19th, that submission, is approved, that's the only way I could tell.

Q. That's very clear. Thank you.

But, anyway, there is a '99 RiskMAP here. If we found an FDA letter that approved this one submitted here, that would give you some assurance that this is the one, the '99 one, that was in effect when you arrived, right?

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: It appears that way, but I'd have to go word by word.

BY MR. CRAWFORD:

Q. And also see -- yeah, see the sequence resulting in an FDA approval letter, right?

A. That's correct.

Q. So it does say on this letter, February 10th, 1999, from Anesta, Reference is made to the November 4th, 1998 approval letter for the Actiq NDA. Specific reference is made to your comments concerning any proposed changes to the current risk management program, RMP, which is dated November 4th, 1998. Since the RMP is considered an integral part of the approved NDA, we draw your attention to the revised RMP included in this submission. We trust that it will meet with your approval.

So they are seeking -- you're interpreting this as they're submitting this attached RiskMAP for the FDA approval with any changes they had?

A. Right. And you don't --

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for

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speculation.
Go ahead.
THE WITNESS: And you don't know that without seeing correspondence from the FDA.
BY MR. CRAWFORD:
Q. We'll look for that.
I think -- I think -- my recollection, I want to see if this may be your recollection, if you went back and reviewed these, I know you weren't here at the time, but I think they dropped Abbott as a marketing partner at this time, and that may have been the change that they requested.
Does that refresh your recollection?
A. That sounds -- that sounds -- I know there was a situation about dropping Abbott. I just don't know if there were any other changes to it.
I don't think there was anything substantive. But, again, there may be some operational things. I just

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don't know, without looking at it word by word.
Q. Okay. Sounds like we have a missing piece there.
It looks like, if you look at Page 7855, that this packet does attach an FDA-approved RMP dated November 4th, 1998, at Page 19-124, which was the original RiskMAP.
Would that be how you would understand this document?
A. Yes, that's how I would understand that.
Q. And, in fact, when you go to Page 124 -- or, actually, 125 -- well, let's see.
124 says, FDA approved RMP, November 4th, 1998. Note: The attached RMP was included in the November 4th, 1998 facsimile from FDA. See November 4, 1998 approval letter.
And then the next page is the risk management program, November 4th, 1998.

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Does that look like what could be the approved, original RiskMAP?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: I'm just -- I'm seeing what you're seeing.
It looks like this is FDA approved RMP November 4, 1998. So I'm assuming this is the first. I'm assuming there was a revised one of February 9th, 1999.
And what date is this?
BY MR. CRAWFORD:
Q. That they submitted with this packet, right?
A. Right.
But I don't know if it was ever approved.
Q. And the missing link is finding whether there was an approval letter of this particular one, right?
A. Correct.
Q. If we found it, that would

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give you some assurance that this, in fact, was the one in operation, at least on the date of approval?
A. They -- likewise, they may have -- if I remember correctly, they may have said the same thing, that we submitted -- there may not be an approval letter, is what I'm trying to say. I don't know if the FDA came back and approved it.
Q. All right. Let's go to the next document. This is 1140.
MR. JENSEN: Exhibit-13.
- - -
(Whereupon, Teva-Marchione Exhibit-13, TEVA_MDL_A_08531805-810, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. So here we marked as document TEVA_MDL_A_08531805, Exhibit-13.
It looks like a standard operating procedure, SOP-0001053, dated

February 11, 2005.
And the SOP is called, Marketing Support of the Actiq Risk Management Program. And approvals are noted here, including your name, of February 11th, 2005.
Do you recall being involved in approving this particular SOP about the marketing support of Actiq risk management program?
A. I actually don't remember.
Q. But your name is on here.
And do you have any reason to doubt that this is the approved program and that you had -- at least had a hand in the approval?
MR. DIAMANTATOS: Objection. Form.
Go ahead.
THE WITNESS: I can only assume that I -- you know, but I just don't remember. But it says here that I approved, so I'm assuming that the database copied

that.
BY MR. CRAWFORD:
Q. So in the regular course of business, if -- you've been involved in getting SOPs approved there at Cephalon, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: In some cases I've approved SOPs, yes.
BY MR. CRAWFORD:
Q. So, and then this -- and would this be the normal format that you would see after an approved SOP came out, with the approvals and the attachment document?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: So we switched over to an electronic system. So I may have never looked at it this way.
BY MR. CRAWFORD:
Q. All right. Okay. So

Paragraph 1, or the top, says, Purpose and scope: The procedure outlines marketing's responsibilities for the Actiq risk management program, RMP, and NDA approval letter. The intent of the risk management plan is to support the approval of Actiq and to assure patient access while addressing the potential risks associated with appropriate patient selection, child safety, diversion and abuse.
And it does say, Departments affected, marketing, sales, global product safety, regulatory affairs and legal.
So do you interpret this or understand this document to be an SOP, a standard operating procedure, encompassing marketing's responsibility with regard to the Actiq risk management program?
A. That's what the document says.
Q. And is that your

understanding of what this is?
A. Yes, that's my understanding.
Q. And there is a section called, Groups of Prescribers, 4.5.
And at this point in time, you're still writing the quarterly reports reporting to the FDA on the Actiq risk management program, right?
A. Yes.
Q. And one of the sections of the RiskMAP is 9.1.2 that we've gone over regarding groups of prescribers and when -- when a group goes above 15 percent of Actiq use, that certain actions are to be taken with regard to education of that group through a professional society, right?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Yep, that's correct.
MR. DIAMANTATOS: Mischaracterizes the exhibit.

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Go ahead.
THE WITNESS: I'm sorry, could you repeat the question?
BY MR. CRAWFORD:
Q. All right. One of the sections of the RiskMAP is 9.1.2, that we've gone over, regarding groups of prescribers, and when a group goes above 15 percent of Actiq use, that certain actions are to be taken with regard to education of that group through a professional society, right?
MR. DIAMANTATOS: Same objections.
THE WITNESS: Nontargeted groups, right.
BY MR. CRAWFORD:
Q. Right. Nontargeted groups.
And that's found in Exhibit-7, if you wanted to confirm that, on Page 27.
So what I want to do is just go through this section and see if you can maybe give your understanding of how

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the process was to apply with regard to targeted and nontargeted groups.
It says, The Actiq RMP Section 9.1.2 requires intervention for suspected off-label use in major physician group populations. The three-digit diagnosis code data is evaluated by market research each quarter. Any physician specialty category, other than those related to oncology, hematology or pain specialists (including pain medicine, anesthesiology, anesthesiology pain medicine, physical medicine and rehabilitation and palliative medicine), exceeding 15 percent of total mentions is highlighted. The highlighted report is reviewed by representatives from global product safety, regulatory affairs, sales and marketing. If needed, a letter concerning -- in other words, regulatory affairs, that's you, your department would review the highlighted report, right?

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A. Yes.
Q. Okay. Do you recall that being the process back then?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Yes.
BY MR. CRAWFORD:
Q. Okay. If needed, a letter outlining prescribing concerns and the offer to conduct an educational program, in conjunction with a professional society meeting or other national setting, to the applicable professional organization (e.g., American College of Surgeons, American Academy of Physical Medicine and Rehabilitation) is drafted and circulated by marketing.
Upon acceptance of the reviewing departments (legal, regulatory affairs, global product safety, and marketing) this letter will be sent to the applicable organization. Responses received from the professional organization are filed with the letter.

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Regulatory affairs includes a copy of this correspondence in the quarterly report to the FDA.
So any letter that goes out is supposed to be included in the quarterly report, right?
A. That's what it says here.
Q. And that's your letter you send, right?
A. No, I don't send it. I send it to the FDA, but I don't send it out.
Q. All right. Well, you author -- you're the signatory of the quarterly report, right?
A. Of the report, yes.
Q. Right. And that gets sent to the FDA?
A. That's correct.
Q. And that's what they're referring to here, right, the quarterly report?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

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THE WITNESS: I misunderstood. I thought you meant the correspondence.
BY MR. CRAWFORD:
Q. No, no, not the correspondence to the doctor.
But the report reporting on it, you were the author of that?
A. That's correct.
Q. Program compliance is the responsibility of the Actiq brand leader.
So what program, do you know, this SOP that you signed off on, what program are they referring to?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I'm sorry, what are you talking about? Program?
BY MR. CRAWFORD:
Q. The last sentence says, Program compliance is the responsibility of the Actiq brand leader.
I'm just wondering what

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program this refers to.
A. I didn't -- I didn't write this, but I'm assuming they mean the compliance to doing these activities.
Q. Got it.
So that would be the Actiq brand leader, that's the marketing department, right?
A. That's my interpretation.
Q. And do you know who the Actiq brand leader was at this time?
A. I don't remember. It could be Andy Pyfer or Michael Richardson. I'm not sure which.
Q. All right. Now, so it looks like to me, and I just want to confirm that this is right, that certain specialties are exempted from this 15 percent requirement, examining it, right?
A. That's what it says here.
Q. And that would be which groups?
A. Well, you read it. So it's -- this says including, so I

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can't -- I don't know all the specific groups. It's in categories -- it's general categories here.
Q. Well, it says, Any physician specialty category other than those related to oncology, hematology or pain specialists.
And pain specialists include pain medicine, anesthesiology, anesthesiology pain medicine, and physical medicine, rehabilitation and palliative medicine.
Those groups are basically exempted out; you don't do any examination, under this procedure, whether those groups are prescribing off label in a manner where the total prescriptions in that group exceed 15 percent of the Actiq --
A. So that's the targeted group.
Q. Right.
A. So this is basically saying the same thing as the RiskMAP, it's the

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nontargeted group which then exceeds 15 percent.
Q. Well, the RiskMAP mentions nothing about targeted or nontargeted groups, right?
A. I thought it did.
Q. Take a look at 9.1.2.
This is Cephalon's way of implementing it, but it really doesn't talk about exempting out targeted groups or anything like that, does it?
That's exhibit -- you pulled it out there, Exhibit-7, Page 27, at the bottom.
I'll just read it for the record. It says, If groups of physicians such as a particular specialty are identified as having prescribed Actiq inappropriately, and those prescriptions represent the potential off-label use greater than 15 percent of total Actiq prescriptions, Cephalon Inc. will contact the appropriate professional society (i.e., American College of Surgeons,

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American Society of Anesthesiologists).
That's the language in the RiskMAP, right?
A. Just give me one minute, please.
Q. Page 27.
A. No, I know what it says on 27. But, remember, we combined it.
So I just want to -- we were talking about targeted earlier. That word was used in some document.
Q. 8.2.1 is what you're talking about?
A. 8.2.1? Maybe it was in the report.
So what I explained before is that there's targeted groups and nontargeted groups. So they identified the target groups where they feel that cancer patients go to see their physician, it may not necessarily be oncologists, it could be others. And I think that's what's included in this general list here of pain meds,

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anesthesiologists, anesthesiology pain med, physical med, rehab and palliative care. So they must have done some analysis and said, cancer patients go to these doctors.
So what they're saying is that if there's any physician groups that don't fall in that general umbrella, if they go outside -- if they prescribe over 15 percent of the total, then that is the targeted group, I think we referred to that earlier, and that, then -- that they would go and go to the group -- you know, whatever, I'm making this up, but let's say it's psychiatrists, and they would go to the psychiatry -- you know, American Association of Psychiatry and try to say -- you know, let them know that we want the list of your doctors to let them know about Actiq and how it should be used.
Q. So --
A. That's my interpretation.
Q. So if psychiatry, as a

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nontargeted group, if total Actiq prescriptions exceeded 15 percent, then that would trigger the -- 15 percent off label, then that would trigger the duty --
A. That's my --
MR. DIAMANTATOS: Objection to form.
THE WITNESS: -- understanding.
MR. DIAMANTATOS: Objection to form. Foundation.
Go ahead.
BY MR. CRAWFORD:
Q. -- the duty to approach a professional society?
MR. DIAMANTATOS: Same objections.
THE WITNESS: That was my understanding.
BY MR. CRAWFORD:
Q. Okay. And those are the nontargeted groups, right?
A. So -- yes. Yes.

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Q. So the targeted groups, they are targeted groups because they are appropriate targets for detailing, right?
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. Is that why they're called targeted?
MR. DIAMANTATOS: Objection. Form. Speculation. Foundation.
THE WITNESS: That was my interpretation.
BY MR. CRAWFORD:
Q. Okay. So if you're in a targeted group, say, these pain specialists, anesthesiologists, et cetera, there's no analysis that's done by the company, under the SOP, whether -- what percentage of doctors within those targeted specialties prescribe Actiq off label to see if that total amount potentially exceeds 15 percent of the total Actiq prescriptions, right?
MR. DIAMANTATOS: Objection to form. Foundation.

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THE WITNESS: My interpretation -- my read of the RiskMAP is that there was no -- there was no requirement for that. I don't know if they did analysis on that.

BY MR. CRAWFORD:

Q. But, again, the RiskMAP doesn't -- basically, it does say that one of the potential societies you would go to is the American Society of Anesthesiologists, if their total off-label prescribing exceeds 15 percent.

So the FDA, or the RiskMAP, at least, contemplates that you might go to the anesthesiologists if their prescribing is over 15 percent off label, right?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.

THE WITNESS: I think at the time there may have been -- the FDA interpreted that you wouldn't

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go to an anesthesiologist if you were a cancer patient.

And I don't know how -- to be honest, I don't know how they determined the targeted versus nontargeted. It's a commercial question.

BY MR. CRAWFORD:

Q. Right. So that -- again, this looks like it's in the sales and marketing world, because that's what this SOP applies to, right?

So you relied on sales and marketing to make a determination of what the targets were and nontargeted groups?

A. I know that our legal group, then, worked more closely with sales and marketing to work with them to understand their practices.

Q. But you, in regulatory affairs, were not in charge of trying to figure out who is targeted or nontargeted or how to divide this up?

A. That's correct.

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Q. You were just simply reporting the results to the FDA, as they filtered up from sales and marketing?

A. I mean, I would have questioned if, again, gynecology was on there or something.

But I just -- or some unusual group. But I didn't go into the details of how they determined that.

Q. But your understanding of the process was if they are in a targeted group, like these oncologists, hematologists and pain specialists, they were set aside, no analysis was done of their off-label marketing --

MR. DIAMANTATOS: Objection.

BY MR. CRAWFORD:

Q. -- as a group?

MR. DIAMANTATOS: Objection. Asked and answered. Repeatedly. The same question, the same answers, repeatedly.

THE WITNESS: I think that's as far as I can take it.

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I mean, I can't tell you anything else, because I -- you know, there was -- there must have -- you know, I believe our legal group evaluated how they were determining that, because it was raised at the audit.

So at that point --

BY MR. CRAWFORD:

Q. I'm not asking how it's determined -- I'm sorry to interrupt -- how you determined which groups are the targeted groups.

I'm just saying, once they've listed the targeted groups here, they never did -- for the purposes of 9.2.1 -- or 9.1.2, they never -- they set those aside and didn't do an analysis, within those groups, of what percentage or what off-label marketing or prescriptions was done, right?

MR. DIAMANTATOS: Objection. Form. Vague. Foundation. Calls for speculation. Asked and

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answered.
THE WITNESS: I don't know. It was done within commercial, so I don't -- I can't answer that.
BY MR. CRAWFORD:
Q. Well, I'm just trying to see what your interpretation -- I mean, you have -- you have responsibility of reporting on this provision to the FDA.
So it just says that any physician specialty category, other than those related to oncology, hematology or pain specialists, that exceed the 15 percent of total mentions is highlighted.
So it looks like that they have excepted out those targeted groups from the 15 percent analysis, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered multiple times.
THE WITNESS: That's my interpretation. And, you know, they -- that's my interpretation.

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BY MR. CRAWFORD:
Q. All right. And let's mark the next exhibit, then.
MR. CRAWFORD: 1693.
MR. JENSEN: This is Exhibit-14.
- - -
(Whereupon, Teva-Marchione Exhibit-14, TEVA_MDL_A_08242504-505, with attachment, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. It looks like these are the -- take a look at this here.
We've marked an e-mail chain. It looks like you're on the one dated May 13th, 2004, from Michael Richardson to Carol Marchione and others, Andy Pyfer; data for 15 percent Actiq prescription meeting.
If you go down right to the middle, under, Answers: Attached is the

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relevant data regarding the Actiq RiskMAP Sections 8.2.1, 8.2.2, 9.1.2. The info shows prescribing by specialty and compares Actiq prescribers with overall opioid prescribers.
So if you could just take a look at this. And there is a colored chart attached to it breaking down primary specialties, Actiq prescriber count, Actiq prescription count, Actiq prescriber percentage, and Actiq prescription percentage.
Is this the chart of specialties that your sales and marketing department, or the company, was looking at to ascertain the 15 percent threshold?
A. That's what I believe it is.
Q. And if you look at the chart, it looks like there is kind of a key in the back of the chart here, on Page -- it must have been an attachment, like a native spreadsheet, so it didn't get a Bates number. But there is a chart on the back with the code to the -- the

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key to the code.
But it looks like, if you look at the first page of the chart, AN and APM, they are both pain anesthesiologist categories, right?
You may need your magnifying glass for that.
A. Yeah, anesthesiology and --
Q. Look, you can look up here on the screen. It might be easier.
A. Actually, I can see.
APM, it says management, so I'm deducing it's pain management.
Q. And AN is anesthesiology.
So anesthesiology, total prescriptions is 20 percent, or 19.57 percent, that exceeds the 15 percent, right?
But it's an excepted category, so you did not do an analysis of whether any of that was off label, right?
A. I may not have. I don't know if -- you know --

Q. Right.
A. -- I didn't do the analysis.
Q. But under the process we just read, that would have been -- that would not have been one of the categories where it's highlighted whether it's above 15 percent, right?
A. That's my interpretation.
Q. And the APM, that's another pain group, that's 12.38 percent.
You know, if you combine those, that's 31 percent of the prescriptions are with these pain specialties, right, anesthesiology and -- it looks like some type of pain management, right?
A. You know, I'm just hesitant. I don't know what the difference between Actiq prescriber and Actiq TRx means.
What's TRx?
Q. I think it did come out. I think prescriber is the percentage of prescribers -- of total prescribers, and then the percentage is the percentage of

the prescriptions that are written.
So 12 percent of the doctors prescribing the drug are anesthesiologists, and they are prescribing 19.57 of the total prescriptions.
Does that --
A. Okay. Yeah --
Q. -- kind of help you interpret that?
A. -- that makes sense.
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I think that makes sense.
BY MR. CRAWFORD:
Q. So if we look down further, family medicine, it's above 15 percent for the prescriber percentage, but it's at 11 percent for Actiq prescriptions, right?
That's the third-to-last one, FM?
A. Right. I see that.

Q. And my question is, as you go to internal medicine, which is IM, a little over halfway down on the next page, that's at 8 percent of prescriptions.
So wouldn't internal medicine and family medicine, wouldn't they both be kind of primary care doctors?
Shouldn't they be combined as a group, or is that something you left to the marketing department to determine?
MR. DIAMANTATOS: Objection to form, foundation.
THE WITNESS: That was -- that was evaluated with marketing and legal.
BY MR. CRAWFORD:
Q. All right. So are these -- would you agree with me that if you've taken out, from looking at the 15 percent threshold for these, quote, targeted groups, and put them aside, and then evaluated all the rest here to see if

they rose between the 15 percent threshold, wouldn't you agree with me that these are so cut up that none of them really would realistically rise above 15 percent, so you would never really have a reporting -- you would never really report anything to the FDA, because you would never have a situation where it goes above 15 percent?
MR. DIAMANTATOS: Objection. Form. Argumentative. Foundation.
THE WITNESS: I mean, I think you can look at it the other way, that it didn't -- I mean, there was no -- there was no algorithm given to us by FDA in how to analyze that.
So, you know, I would look at this and say, we did not hit 15 percent, based upon the way we interpreted it.
And I thought the RiskMAP actually alluded -- 15 percent of -- so I find this as what we

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were supposed to do; you know, acceptable within what the parameters of the RiskMAP said.
BY MR. CRAWFORD:
Q. So the marketing department was -- well, strike that.
You would agree, though, that the goal of the RiskMAP was to minimalize the amount of off-label marketing, and if there was a problem with off-label marketing, that some type of intervention would take place?
Is that really kind of the goal of the RiskMAP, or one of them?
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. In your view?
MR. DIAMANTATOS: Same objection.
THE WITNESS: What's being prescribed and what's being marketed are two different things.
So I think -- yes, I would

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agree that that's what the RiskMAP is supposed to do. But how people are actually prescribing doesn't necessarily mean that they were marketed to. It means they were -- a fentanyl product and they're trying to address pain.
So I feel that you can't necessarily equate the two.
BY MR. CRAWFORD:
Q. But definitely the FDA was concerned about off-label marketing when it approved it with a RiskMAP, right?
That was one of the things that they were -- expressed concern about in the RiskMAP, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.
THE WITNESS: I mean, I would agree with you that the RiskMAP -- you wanted to target marketing to the appropriate people.

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BY MR. CRAWFORD:
Q. And so the RiskMAP also wanted the company to take some type of corrective action, educational action, if it learned that there was an inordinate amount of off-label use, right?
MR. DIAMANTATOS: Objection. Form. Vague. Foundation. Calls for speculation. Asked and answered.
THE WITNESS: As I said previously, any time that we learned of off-label use from a prescriber, they were informed by -- I believe by a visit and a letter to review the prescribing information.
BY MR. CRAWFORD:
Q. But also the RiskMAP required, if you learned that groups of prescribers -- you may not have known their names, but if you knew the groups of prescribers were prescribing off label at a certain threshold, that would

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trigger obligations, on your company's part, to go educate them as a group, not -- you know, not to send them individual letters, but to educate them as a group somehow, even if you don't have direct knowledge of a particular doctor in that group was prescribing off label, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
Go ahead.
THE WITNESS: I think the SOP addressed that. That's what it says in the SOP. You just pointed it out to me, from the marketing group, that that's what they would do.
Right? I mean --
BY MR. CRAWFORD:
Q. Right.
But the RiskMAP, the intent was not to just send individual letters when you found out about a doctor who did

it -- that was one aspect, right?
But, remember, it's a redundant program, right?
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. They had redundancies within it; you remember reading it, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered repeatedly.
THE WITNESS: The SOP says that. You read it to me. That -- their marketing SOP says that they would do that, right?
BY MR. CRAWFORD:
Q. No. I'm talking about redundancy.
There are redundant mechanisms within the RiskMAP to make sure that the drug is safely used, right?
And the redundancy here is not only sending letters to individual prescribers that you learn are prescribing off label, but educating them

on the proper use.
But if you learn that groups of prescribers are, that's 9.1.2, there are mechanisms in place to educate that group of prescribers, even if you don't know of particular ones are prescribing off label, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered multiple times.
THE WITNESS: If you refer back to the SOP that marketing -- it says that. It says that they will go as a group. The one you just pointed out to me, the marketing one that had approval, that's what it says it will do.
BY MR. CRAWFORD:
Q. Right. I'm not saying -- I'm not talking about the SOP. I'm just -- I'm talking about the RiskMAP has that function.
You were just talking about

writing a letter. But it also has the function of education, and that's the RiskMAP.
And you're saying that the SOP implements that provision, right, 9.1.2 --
A. Right.
Q. -- right?
A. Yes.
MR. DIAMANTATOS: Objection to form. Mischaracterizes testimony. Calls for speculation. Asked and answered.
MR. CRAWFORD: Let's go to 1143.
MR. JENSEN: This will be Exhibit-15.
- - -
(Whereupon, Teva-Marchione Exhibit-15, TEVA_MDL_A_01405193-5194, was marked for identification.)
- - -
BY MR. CRAWFORD:

Q. We marked here an e-mail string. I want to focus in on -- let's start at the second page.
It's an e-mail from Tracie Parker to Michael Richardson and others, and you are cc'd on this as well. Subject is, Prescribing specialties - 15 percent. It's TEVA_MDL_A_01405193.
Ms. Parker is your -- she reports to you, correct, in the regulatory department?
A. She did.
Q. Yes. All right.
So she writes, Michael, in follow-up to the meeting today to review the RMP, attached are the data from the 18th and 19th RMP quarterly reports, re the breakdown of the prescribing specialties. You will see that both AM and PM are above 15 percent but are considered to be targeted specialties. Dan, correct me if I'm wrong. To date we have been able to make the statement that none of the nontargeted physician

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specialties have exceeded 15 percent. The data is forwarded to me each quarter by Dan Winkelman, Mark Solomon.

Dan Winkelman and Mark Solomon, is that -- are they in the marketing department? Who are they?

A. I think so.

Q. So, basically, it's reported to the FDA -- what she's saying, really, here -- is it your interpretation that she is saying that you only report to the FDA if a nontargeted specialty is identified as exceeding 15 percent?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

THE WITNESS: That's what I explained before. That was -- that was our interpretation of 9.1.2.

BY MR. CRAWFORD:

Q. Okay. And if -- the nontargeted specialties, is the assumption made that those prescriptions

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are off label, if they're in that?

A. The nontargeted would be the groups that wouldn't -- wouldn't be usually associated with cancer patients.

Q. Right. And so the presumption is that if one of those groups exceed the 15 percent, then you can assume that, potentially, that's over 15 percent of the total Actiq prescriptions being prescribed off label, and so that's when the education function starts, correct?

MR. DIAMANTATOS: Objection. Form.

THE WITNESS: That's my understanding.

BY MR. CRAWFORD:

Q. Okay. And then, again, anesthesiology and PM are above 15 percent, those are the targeted groups, anesthesiology and pain management.

But there's no reporting requirement because they're targeted, right?

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MR. DIAMANTATOS: Objection. Asked and answered over and over again.

MR. CRAWFORD: I'm just asking in relation to this.

MR. DIAMANTATOS: Then make that clear from your question, because you've asked these identical questions repeatedly on the record.

THE WITNESS: That was my interpretation. It's all -- it's all kind of the same thing.

BY MR. CRAWFORD:

Q. All right. So going back to the first page.

Mr. Pyfer writes to Michael Richardson, copying you, My opinion would be to change this aspect of the RMP and to track only those specialties that we don't want to see prescribing Actiq because their primary patient populations pose a risk (where Actiq is contraindicated). These would be

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dentists, surgeons, minus oncology surgeons, and pediatric specialties, (until we have a label for this population). Wouldn't this make more sense than trying to determine inappropriate prescribing based on a specialty?

And then he writes, How can anyone in this world possibly determine how a pain specialist (whether it is an anesthesiologist, internal medicine, physiatrist, FP/GP, et cetera) is prescribing Actiq? Focusing on and tracking the specialties that are risky specialties, based on our contraindications, is the best way to minimize the risk of Actiq being used in unintended patient populations, isn't it? Ultimately, isn't the purpose of the RMP to minimize the risk in unintended patient populations, not to try to guess how physicians, especially skilled opioid prescribers, are practicing medicine?

So Mr. Pyfer, in effect,

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wants to -- wants to reduce even further the examination of the 15 percent threshold by just looking only whether the contraindicated specialties are exceeding 15 percent, and he lists them there, the surgeons and the dentists and the pediatric specialties, right?

MR. DIAMANTATOS: Objection to form. Calls for speculation.

Go ahead.

THE WITNESS: That's my interpretation of what he's saying.

BY MR. CRAWFORD:

Q. And he's also telling you here that there's no way -- he says, How in the world can you possibly tell, within a specialty, if they're prescribing off label?

That's what he's explaining, right?

A. Right.

MR. DIAMANTATOS: Objection to form. Calls for speculation.

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BY MR. CRAWFORD:

Q. Is that -- is that what he -- and that's what he's telling you is that that can't be done, right?

MR. DIAMANTATOS: Objection to form. Calls for speculation.

THE WITNESS: That's my understanding.

BY MR. CRAWFORD:

A. So is that one reason why, when you took the targeted specialties, that there was no effort made to -- is it your understanding that no effort was made to determine, within those targeted specialties, whether -- what was being prescribed off label.

MR. DIAMANTATOS: Objection. Form. Asked and answered.

THE WITNESS: I don't know enough of how -- you know, the data -- I think the key all comes down to is you don't know, when you're prescribing for somebody, if they have cancer. And the

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reason why you're prescribing -- this is my understanding, whether it's true or not it's my understanding.

BY MR. CRAWFORD:

Q. Fair enough.

A. When you prescribe something, it doesn't say for cancer pain -- it doesn't say what it's for, it's just a prescription.

So I believe the issue is, how do you know if they're prescribing anything for cancer patients? I mean, even a dentist could prescribe it for cancer patients.

So this was the dilemma that is on the table, in terms of how -- how do you sift out who is a target, who isn't? I mean, it was a real dilemma.

And all that I'm reading here is, by introducing this to the FDA -- he's saying try to make the change -- then at least it opens a dialogue, and then you can get the FDA's

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interpretation.

All we had was back in 1998 or '99 the FDA's, you know, limited understanding, before the product was even launched. And as time went on and we learned more, what we were always trying to look for was a dialogue with the agency of how we -- what we were doing. I mean, as I said, we kept trying to do that.

And I feel that we were at least successful in relaying our concerns, our limitations in how to do this, when we went to this July 4th meeting. Because we were very open there, if you look through this whole, huge document that I put together in four days, and read very carefully, is that it was really impossible to really match up, you know, you have cancer with -- with what your prescriber --

So it was a real dilemma in trying to -- in trying to perform the risk management process as much as that

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was initially written.
And we tried to do our best. We tried to do an interpretation. But we really wanted a dialogue with the agency to try to get -- so they could understand what we were up against. And that's what, probably, you're seeing in a lot of these back-and-forth.
And, again, I think we were successful when we did go to the agency to try to explain what our dilemmas were and how we were doing it.
Q. And one dilemma was, Mr. Pyfer's pointing it out, you can't tell, within a certain specialty, what the specialist is prescribing it for, whether it's cancer or noncancer?
A. That's exactly -- that's exactly it.
Q. And that was your understanding, up until this day, is that's not -- that wasn't possible during this time period, right?
A. That's my understanding.

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Like this IMS -- I understood that the IMS database couldn't capture that. I don't know if it can. I can't imagine how. But that's my limited understanding.
Q. All right. And then you respond, Andy, I'm in agreement and I'm trying to think of the best way to support this in the revision to the FDA.
That's a revision of the RiskMAP, right?
A. That's correct.
Q. I think that this point will be a discussion point at a meeting that I'm trying to set up, as suggested by Victor, to discuss the more critical issues with the VP level. I think certain stakeholders, such as you, would be invited. Thanks for your input. Carol.
So you're, at a point, working on a revision to the RiskMAP to the FDA, right, the Actiq RiskMAP?
A. Again, I think we were

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working on it multiple times. I think, at this point, you know, I was saying I want management's decision on this, I wanted -- so new people came, new management people came within Cephalon, and I just wanted everyone to understand it.
And so that's what this is about, especially because my boss was new.
Q. And that's Mr. Raczkowski?
A. Raczkowski. Doctor.
Q. Dr. Raczkowski?
A. I think so, yes.
MR. CRAWFORD: Let's pull up Exhibit -- Document 231.
MR. JENSEN: This will be Exhibit-16.
- - -
(Whereupon, Teva-Marchione Exhibit-16, TEVA_CHI_0043010-0983, was marked for identification.)
- - -
BY MR. CRAWFORD:

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Q. What I'm giving you here is the 2005 Actiq marketing plan, TEVA_CHI_00043010.
This is -- were you involved at all in preparing or reviewing the marketing plans at Cephalon?
A. I don't think so.
Q. And did you review them at all for whether they were complying with the RiskMAP, or did you depend on sales and marketing, or other departments, to do that?
A. This is an internal document to marketing. And I didn't review internal documents.
Q. All right. And you see Andy Pyfer is listed as the first name under product director, right?
A. Yes.
Q. And you agree with me, at least from the front of it, it looks like the 2000 Actiq marketing plan, right?
A. That's what it says.
Q. And this is -- that stick

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there is your understanding of what the Actiq product looks like; that they put in their mouth with the dissolved lozenge at the top, right?
A. That's correct.
MR. DIAMANTATOS: Objection. Did you say 2000 Actiq marketing plan?
MR. CRAWFORD: 2005.
MR. DIAMANTATOS: I think the record --
MR. CRAWFORD: Let the record --
MR. DIAMANTATOS: I heard 2000, and I think that's what the record reflects. I just want to be clear we're talking about the same thing.
MR. CRAWFORD: Thank you. Yes.
BY MR. CRAWFORD:
Q. We're looking at the 2005 Actiq marketing plan.
So if you could look at Page

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22. This plan divides out -- on the top, there are two charts, percent of prescriptions -- TRx is prescriptions, right?
A. That's what you explained.
Q. Is that your understanding of what TRx is?
MR. DIAMANTATOS: Objection. Foundation.
THE WITNESS: I wasn't sure. But that's what you told me earlier.
BY MR. CRAWFORD:
Q. All right. Assuming it's prescriptions, percent of prescriptions by specialty, it lists, basically, five specialties, plus other.
First being oncology, this is for June 2003, is 3 percent. And it lists also for 2004, it's 3 percent. Neurology is 7 percent, and it's at 8 percent.
Now, neurology is a nontargeted specialty, right?

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According to that SOP it didn't fall within one of the targeted specialties, right?
A. It wasn't a subcategory. I don't know how -- you know, I don't know how -- when you have groups of umbrellas, I don't know how they're interpreting this.
Q. But, certainly, it doesn't fall within the SOP list of pain specialists or oncologists?
A. It said examples -- it said examples of pain -- again, this is an internal marketing document.
So I'm not quite -- you know, I don't think I've seen this before. So I don't know how they're delineating things.
Q. Sure. Fair enough. Okay.
But 20 percent is to primary care providers, PCP.
Do you see that?
A. I see that.
Q. That exceeds 15 percent,

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right?
A. 20 is bigger than 15, yes.
Q. And it carries over 21 percent in June 2004.
June 2004 is about the time that you're communicating with Mr. Pyfer here; his e-mail to you is May of 2004.
So this is about the time you guys are talking about this 15 percent level, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: What's the date? Maybe. I'll have to check up -- the dates.
What's the date of this?
BY MR. CRAWFORD:
Q. I don't know if there's a date on the document.
A. So then I can't answer that question.
Q. But I'm just looking at the chart date. It says, June 2004, the prescriptions reference for that date are

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primary care providers at 21 percent, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That's what it says in the document.
BY MR. CRAWFORD:
Q. Do you know if Cephalon reported to the FDA that primary care providers had exceeded the 15 percent level, after June of '04, in any of their quarterly reports?
MR. DIAMANTATOS: Objection. Form. Foundation. Assumes facts.
THE WITNESS: I don't know -- again, I don't know the interpretation. I don't know PCPs were -- was a target or not. It's hard for me to interpret this, because it's out of context to the RiskMAP, and, really, what they're doing and how they're doing it.
BY MR. CRAWFORD:
Q. Well, you depended on the

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marketing department to tell you when a specialty exceeded 15 percent, right?
MR. DIAMANTATOS: Objection. Form. Asked and answered.
THE WITNESS: There was -- the document that you showed me previously, we would get those pages.
I think, then, when that came out, I believe legal reviewed it, and then -- before it came to me. So if it came to me telling me that it exceeded, that's what I would see.
BY MR. CRAWFORD:
Q. Right. So you would not make the determination what specialty exceeded 15 percent; you would either be told by marketing or legal, or a combination of the departments?
A. That's correct.
Q. So you reported -- if nothing was reported to you exceeding 15 percent, it didn't get reported to the

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FDA, because you prepared the reports, right?
MR. DIAMANTATOS: Object to the form.
THE WITNESS: That's correct.
BY MR. CRAWFORD:
Q. You depended on those other departments to let you know what was exceeding 15 percent?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered.
THE WITNESS: Yes. After -- initially, we looked at it. And then afterwards we -- it was reviewed by legal and that's how we got it.
BY MR. CRAWFORD:
Q. "We" meaning you looked at -- okay, you looked at the report. But legal looked at it. Okay.
A. When I first was responsible for the RiskMAP quarterlies, I looked at

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the printouts that we saw before.
As time evolved, and I can't say exactly when, you know, again, Tracie put these together, so it was up to her to get that information. And I believe that somewhere during that time, legal said that they would double-check, as an interim, before it came to us.
Q. And one of the other groups is anesthesiology pain, that's in the targeted group, and that was, it looks like, 55 percent of total prescriptions in June 2003, and it went down to 51 percent in June of '04.
Is that what you interpret the charts to reflect there?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: I mean, I don't know if they were saying this is -- I mean, if this is what they want to do -- this is a marketing plan. I've never seen this before. I'd have to review

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the document.
I don't know where they were going with this. Just seeing diagrams, it's hard for me to tell you definitively what they're trying to do.
BY MR. CRAWFORD:
Q. All right. If you could look at Page 24 of this marketing plan, down at -- actually, Page 24, there's a section called, Physician usage.
Do you see that?
A. I do see it.
Q. And then look at the top of Page 25, it says, Based on physician reporting, 90 percent of Actiq use is for BTP -- that's breakthrough pain, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: That's -- yes.
BY MR. CRAWFORD:
Q. -- outside of cancer.
So what this report is saying, this marketing report, is that 90

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percent of the Actiq use, in their view, is off label for noncancer uses, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. She's repeatedly said she's not familiar with this document.
BY MR. CRAWFORD:
Q. Is that how you interpret the document?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.
THE WITNESS: I mean, I can read it just like you. I have the same interpretation.
BY MR. CRAWFORD:
Q. Does it look like they're saying that 90 percent of Actiq use is for BTP outside of cancer?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered. Calls for speculation.
THE WITNESS: Again, that's

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what it says in this -- that's what it says, if I read it.
BY MR. CRAWFORD:
Q. And then it says, The majority of use, 55 percent of total, is being for chronic back pain.
That's not a cancer indication, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: I'm a regulator. I'm not a clinical person. So that's what it says here. I agree that that's what it says in this document.
BY MR. CRAWFORD:
Q. Then there's a chart that lists distribution of conditions treated with Actiq; the 55 percent back pain is referenced and 22 percent headache.
That's not an indicated condition for Actiq, right?
MR. DIAMANTATOS: Objection.

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Form. Foundation. Calls for speculation.
THE WITNESS: Actiq is indicated for cancer pain.
BY MR. CRAWFORD:
Q. Right. But not headache, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: You want to go through everything?
BY MR. CRAWFORD:
Q. There's just three or four, I want to go through them.
Headache is not an indicated use for Actiq, right?
A. It's not an indicated use for Actiq.
Q. And that's 22 percent, according to this chart, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
BY MR. CRAWFORD:

Q. And then there's FMS/MPS -- actually, do you know what that means? Fibromyal --
A. Maybe. I don't know.
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. Fibromyalgia, myofacial pain?
MR. DIAMANTATOS: Objection to form. Calls for speculation. Foundation.
BY MR. CRAWFORD:
Q. That's not an indicated use in your view as a regulatory specialist in Cephalon, right?
A. That's correct.
Q. And arthritis is 13 percent, right?
A. Total, 13 percent.
Q. That's not -- that's not an indicated use for Actiq, right?
A. That's not an indicated use.
Q. And neuropathy is 12

percent; again, that's not an indicated use, correct?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: That's not an indicated use.
BY MR. CRAWFORD:
Q. And then malignant, that -- malignant is cancer, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: Yeah, I don't -- I don't know specifically how they got this here.
BY MR. CRAWFORD:
Q. Right. But malignancy is cancer, right?
MR. DIAMANTATOS: Same objections.
THE WITNESS: I mean, I'm interpreting just like you are.
BY MR. CRAWFORD:

Q. And you agree with me, I'm interpreting malignancy as cancer; is that something that you agree or disagree with?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered. Calls for speculation. Argumentative.
THE WITNESS: I don't know why it doesn't say cancer pain.
So that's why I don't know how they put that as an umbrella. Why wouldn't they have put cancer pain? I don't know. I don't know the answer.
BY MR. CRAWFORD:
Q. Something normally, in your kind of lay understanding, at least, that malignancy means cancer and nonmalignant -- nonmalignant means not cancer, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.

Argumentative.
THE WITNESS: What do you want me to say? I think I said it all.
BY MR. CRAWFORD:
Q. It kind of comports with the first sentence, it says, 90 percent of Actiq use is for BTP outside of cancer.
So that leaves 10 percent being for cancer, and that chart says 10 percent malignancy. So, probably, it links up that the malignancy means cancer in this document, right?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.
THE WITNESS: Probably -- I mean, you're saying "probably." That's an interpretation.
BY MR. CRAWFORD:
Q. And then CRPS, complex regional pain syndrome, is that an indicated use for Actiq in the label?
MR. DIAMANTATOS: Objection.

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Form.
THE WITNESS: I have never even heard of that before. I don't know what complex regional -- I never heard that syndrome before.
BY MR. CRAWFORD:
Q. But it's not cancer, though?
A. It's a syndrome --
MR. DIAMANTATOS: Objection to form. Foundation.
THE WITNESS: I don't know if it's associated -- I really don't know. I'm not being facetious. I don't know if the syndrome could be associated with cancer.
BY MR. CRAWFORD:
Q. All right. Well, down below that, again, source of the data is an IMS patient chart audit, October of 2003.
Do you see that?
A. I do.
Q. Right below.

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A. I see that.
Q. So it looks like the source of the information was taken from IMS data, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: That's what it says in this document.
BY MR. CRAWFORD:
Q. And that's October of '03, correct? Is that what it says?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: That's what it says.
BY MR. CRAWFORD:
Q. And below, it says, It should be noted that specialty usage tends to fluctuate based on patient presentation and physician recognition of the need for rapid-acting or BTCP/DTP. For example, neurology usage tends to be higher for headache, 97 percent, while

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PCP usage is higher for back pain, 81 percent.
So primary care physicians, PCP, are using it primarily for back pain, 81 percent.
Do you see that?
A. I see it on the page.
Q. Now, below that, it says, Actiq use by specialty.
And it lists malignant pain, back pain, headache, all the conditions that we just went through in that bar chart, and it breaks it down by specialty.
So do you see the specialty anesthesiology and pain, right there in the first column, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
Are you just having her confirm what's in the document she knows nothing about? Is that what your questions are calling for?

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BY MR. CRAWFORD:
Q. Can you answer my question?
A. It says, Anes -- it says, Anes pain in the first column.
Q. Right. And so it looks like this chart, would you agree with me, breaks down the usage amongst the anesthesiologists and pain specialists, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: I mean, respectfully, I'm a regulator. This is a marketing plan. So there may be somebody else that you could talk to that could be more -- I'm not trying to be, you know, abrasive, but --
BY MR. CRAWFORD:
Q. I know.
But Mr. Pyfer told you, in Exhibit-15, that you couldn't break down how the drug was used for what condition

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within a specialty.
Do you remember that in Exhibit-15? He told you that? He said it was not possible?
A. So I -- I don't -- I don't know. I didn't know that.
Q. But didn't he tell you that, right?
A. Did he?
MR. DIAMANTATOS: Objection. Asked and answered.
THE WITNESS: I mean, that was my understanding. I guess what I -- the only thing I can say is my understanding, and I don't know about how IMS works, is you can't tell what, specifically, it's being -- I don't know where they got these numbers. I don't know -- I don't know. I mean, that's what I understood.
Like, when somebody -- just think about it, when you go get a prescription filled, how do you

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know it's for cancer or not, you know, or a headache? They just write -- they write what it is, not what it's for.
So I don't know how they get these numbers.
BY MR. CRAWFORD:
Q. Right. And Mr. Pyfer told you there's no way to know, right?
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. You're trusting your marketing department telling you that, right?
MR. DIAMANTATOS: Objection. Form. Asked and answered. Argumentative. Calls for speculation.
BY MR. CRAWFORD:
Q. Is that right?
MR. DIAMANTATOS: Same objections. Asked and answered multiple times.
THE WITNESS: And then my

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legal department became involved with them, so I'm also trusting my legal department.
And so I don't know. I mean, I just -- there may be a really good response to this, I just don't know the answer.
BY MR. CRAWFORD:
Q. Right. But I'm just asking, Mr. Pyfer, in Exhibit-15, had informed you that you couldn't tell, within a specialty, how it was prescribed.
Do you agree with me that that was what he was conveying to you in Exhibit-15?
MR. DIAMANTATOS: Objection. This is getting to the point of badgering the witness. She's answered the same question repeatedly, counsel. And she's doing her best to respond to the question that you've asked multiple times.
The problem is that you're

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putting documents and asking her things about other people, things outside of her area.
This has now gone beyond the point of you badgering the witness, who's answered your question.
BY MR. CRAWFORD:
Q. Go ahead. You can answer.
A. It says, How can anybody in this world possibly determine how a pain specialist is prescribing Actiq?
And I don't know. There may be -- I don't know how they get these numbers. I think -- you know, really, if you ask an IMS -- I mean, totally objectively, you get an IMS specialist, they could probably tell you. I don't know how that works.
Q. All right. But it does say, Source: IMS patient chart audit, October 2003, right below that, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for

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speculation. Asked and answered.
BY MR. CRAWFORD:
Q. I'm just saying --
MR. DIAMANTATOS: I'm not done with my objection.
Asked and answered repeatedly.
MR. CRAWFORD: I don't think I asked that question. That's for sure.
BY MR. CRAWFORD:
Q. Go ahead.
A. So it says -- it references IMS. And I highly recommend that you talk to an IMS person to understand how they can analyze. I don't know how that happens.
Q. Right. You don't know how, right?
A. Right. I don't.
Q. And so you rely on other people to tell you whether or not it can be done or not.
And Mr. Pyfer told you it

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couldn't be done, right?
MR. DIAMANTATOS: Objection. Form. Argumentative. Asked and answered.
THE WITNESS: But -- I think we can do this forever, without having, I think an objective IMS person, you know, take away from fentanyl, from anything, and find out how you can do that.
It may be something that Andy is generalizing. I don't know how it was done. I'm really not trying to be --
BY MR. CRAWFORD:
Q. I know you don't know how it's done. I know that.
But my question is, he told you it couldn't be done, right? That's all I'm asking. It's yes or no.
A. We read it into --
MR. DIAMANTATOS: Objection as to instructing the witness how to answer the question. She's

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answered the question as to what Mr. Pyfer told her in the e-mail. She's repeatedly answered that question, counsel. Same objection.
BY MR. CRAWFORD:
Q. So you would agree with me that Mr. Pyfer told you that it couldn't be done, right?
MR. DIAMANTATOS: Objection. Asked and answered.
Go ahead and answer.
THE WITNESS: I'm reading from his e-mail. If you want me to read what he said, that's all I can do.
BY MR. CRAWFORD:
Q. Sure.
A. Is that -- he says, How can you possibly determine how a pain specialist is prescribing Actiq?
And he was writing this not to me specifically. He was writing to Michael Richardson, who works for him. I

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was copied on it.
Q. But you responded to him, correct?
And you said, Andy, I'm in agreement. And I'm trying to think of the best way to support this in the revision to the FDA.
Right?
So you took what he said and were trying to incorporate it into what you were revising to the FDA, right?
MR. DIAMANTATOS: Objection. Form. Argumentative. Asked and answered. It mischaracterizes her response to the e-mail, which was not read in its entirety.
Go ahead and answer the question.
THE WITNESS: If I was going to revise -- if I was going to send a revision to the FDA, I'd have to send a white paper supporting why we're saying that, and then I would have all the

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documentation, including input from IMS, to understand that.
So we -- I don't know if we ever got that far, or where it stood.
But I would have to understand IMS and how they do the research and how they categorize and -- you know, I don't know whether he's taking this as buckets, or if they are giving him specific analysis. I just -- that's as good as I can do.
BY MR. CRAWFORD:
Q. But you depend on the sales and marketing department to give you accurate and honest information, do you, when you're preparing a RiskMAP or a revision to the FDA; is that right?
MR. DIAMANTATOS: Objection. Form. Asked and answered at least five times.
THE WITNESS: I depend -- we're all trained in ethics when

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we -- where we work. And I depend on everyone, just as, hopefully, they depend on me to be the same way.
BY MR. CRAWFORD:
Q. And Mr. Pyfer is the first person listed on this 2005 Actiq marketing plan where, on Page 24, they're breaking out Actiq use by specialty and breaking out the use amongst anesthesiologists and pain specialists, and only 13 percent is used for malignant pain, on label; the rest off label.
Would you agree with me there?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Argumentative.
THE WITNESS: I can read what you say. I don't know how it got there. I don't know the background behind it.
So that's all I can do is agree that that's what is on the

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page.
BY MR. CRAWFORD:
Q. Okay.
A. Okay.
Q. Thank you.
MR. CRAWFORD: Do you want to take a break?
MR. DIAMANTATOS: Why don't we do that.
VIDEO TECHNICIAN: Going off the record at 2:22 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 2:38 p.m.
BY MR. CRAWFORD:
Q. Ms. Marchione, I just wanted to ask -- we looked at that marketing plan -- did anyone from marketing ever tell you, in this 2004 time period, that approximately 90 percent of Actiq was being prescribed off label for noncancer

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pain?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: Did anybody tell me? I can't remember.
But I did know that there was a considerable amount of off label, not marketing, but sales.
BY MR. CRAWFORD:
Q. Sales. Okay.
And just a couple preliminaries I forgot to take care of.
You're represented here by counsel at this deposition, right?
A. Yes, I am.
Q. And are you being paid at all for your time, by anyone?
MR. DIAMANTATOS: Objection. Form.
Go ahead.
THE WITNESS: No, I'm not being paid today to be -- to be deposed.
BY MR. CRAWFORD:

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Q. How about for the prep, did you meet with your counsel or any lawyers to prepare for this deposition?
A. Yes, I did.
Q. And were you paid for that time?
A. Yes, I was.
Q. And how much were you paid?
A. I was paid the rate -- my hourly rate as a consultant.
Q. And what's that?
A. It's $275 an hour.
Q. And how many hours did you meet before the deposition?
A. God. I want to estimate -- it was three days, but they weren't whole days. I don't know, maybe 12 to 15.
Q. All right. Thank you.
MR. CRAWFORD: We marked the next exhibit.
MR. JENSEN: Exhibit-17.
- - -
(Whereupon, Teva-Marchione Exhibit-17,

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TEVA_MDL_A_01159525-527, was marked for identification.)
- - -
MR. CRAWFORD: It's Document 599.
BY MR. CRAWFORD:
Q. This is document TEVA_MDL_A_01159525.
It's a letter from Dave Brennan to Kerry Woods of the FDA, dated February 23rd, 2004.
Have you ever seen a copy of this letter before?
A. No, I have not.
Q. Mr. Brennan writes to Ms. Woods, This letter is to inform you of certain compliance issues at Cephalon, Inc. of 145 Brandywine Parkway, West Chester, PA. As a former employee responsible for conducting quality assurance audits, I'm aware of violations for which the company has taken no action. In fact, I believe my employment was terminated for publishing a report

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within the company detailing noncompliance in at least one of these areas.
Were you aware that Mr. Brennan had been terminated from Cephalon?
MR. DIAMANTATOS: Objection. Form. Foundation.
Go ahead.
THE WITNESS: I knew he left. I didn't know he was terminated.
BY MR. CRAWFORD:
Q. You know he left around this time period, after he did the report?
A. I didn't -- I didn't connect any correlation. So I didn't -- you know, I just didn't remember.
Q. And do you know a gentleman, at all, by the name of Tim Sheehan?
A. Yes. I think Tim was his manager.
Q. And do you know if he was -- had left the company about this time?

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A. You know, I don't remember.
Q. Do you know if he was terminated?
A. No, I don't.
Q. Mr. Brennan continues, As with any company, there are several things that need to be corrected, some more serious and some less. I am aware of several issues, but the most important, and the one for which I believe I was terminated, regards the Actiq (oral fentanyl citrate on a stick) risk management program.
This program is a condition of approval in the Actiq NDA, detailing several obligations the company has regarding the monitoring and reporting of marketing, prescribing habits, adverse events, pharmacy compliance and patient education.
He continues on, I published an internal audit report, about 1 December 2003, detailing the points for which the company was not in compliance.

I do not have a copy of the report available to me at this time. My recollection is the noncompliance in the report includes, among other things, the following points.

And then you'll see that he does raise the point about the customer surveys of the top four pharmacies and the welcome kit.

Do you see that in the first point?

A. I do see that.

Q. And he does continue -- I want to continue down to the third point.

He says, The drug is approved for a very narrow therapeutic category. The RMP is designed to assure that the drug is not marketed outside the approved use. The company is required to monitor physician prescribing habits. Physician specialties are described as either representing appropriate patient selection or inappropriate patient selection. If the ratio of prescriptions

by specialties representing inappropriate patient selection exceeds 15 percent of the total prescriptions written, the company is required to report this to the FDA and required to conduct physician training programs for the offending specialties.

And he writes in the first bullet point, In one section of the quarterly reports to FDA, the company simply states that no individual specialty exceeds 15 percent. This statement applies to the three or four specialties designated to represent appropriate patient selection, as well as the dozen or more specialties representing inappropriate patient selection.

And then he says, In the section corresponding to the specialties representing appropriate versus inappropriate patient selection requirement, nothing is reported. This section is routinely omitted from the

report.

You recall in the report we looked at that you prepared, Section 9.1.2 was, in fact, omitted from that report, although you mentioned it had been reported elsewhere, right?

MR. DIAMANTATOS: Objection. Form. Foundation. Misstates the witness's testimony. Asked and answered.

THE WITNESS: So if I can just back up.

If you saw, like, that table that you showed me where we had to go to the very back page, with the definitions of what the different prescribers were, those are the reports that we used to see in order to make that statement.

Unfortunately, Dr. Brennan -- I mean, Mr. Brennan didn't do a very thorough job, that I can tell, when he did this audit. He didn't go to source

documents. And, to me, that's kind of 101 on a QA basis.

So if he worked for me, he would have been fired, whether -- I mean, I shouldn't laugh about this, but you go to source documentation in order to find out what was correct and what isn't.

I mean, my interpretation of what he did was just look at the report versus what was supposed to be reported, and not really go into the detail.

So he didn't really get into the detail of what was available, what was being reported, how things were interpreted.

So what -- I'm looking at this, it's not very thorough in terms of his interpretation of what we had available, what was said, what wasn't.

He never looked at that table that, you know, we were

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talking about, showing where the percentages were.
BY MR. CRAWFORD:
Q. Can you grab the table that you're referring to? I just want to make sure I know what exhibit that is.
Was it 14 you were looking at?
A. It was the one that had all the numbers, and then the last page had the definitions. Do you remember that one?
Q. Yeah, Page 14 -- or Exhibit-14.
A. Exhibit-14. Yes.
This is -- so that -- this is the kind of report -- this is from 2004. But when I was working on these originally, we would get these and they were always -- and you pointed out, that they were all below 15 percent.
And that's what we -- what we would normally use to make that statement.

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Q. But how do you know he didn't look at these reports?
He mentions 85 specialties that the company used, right?
A. Because --
MR. DIAMANTATOS: Object to form. Foundation. Calls for speculation. Argumentative.
THE WITNESS: Because I looked in his memo. I don't think he referenced that.
He referenced everything he looked at, and I don't see anything about IMS data.
Documents and records. He didn't even -- yes, there's nothing in here about looking at IMS data. He didn't go to source documents.
BY MR. CRAWFORD:
Q. So what would he have found that may have changed his mind about how Cephalon applied the 15 percent?
A. He would --

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MR. DIAMANTATOS: Objection. Form. Calls for speculation.
Go ahead.
BY MR. CRAWFORD:
Q. What do you think he should have looked at that he didn't look at?
A. The -- and this was 2004 --
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: These tables.
BY MR. CRAWFORD:
Q. And what would he have found there that might have changed his view of compliance with that provision?
MR. DIAMANTATOS: Objection. Calls for speculation. Form.
THE WITNESS: The targeted -- he would have sat down and figured out how they identified target versus nontarget, where the numbers would come to.
BY MR. CRAWFORD:

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Q. But he does say, in Number 13 of his report, I think you just had that.
He says, There are approximately 85 specialties reported, three of which are included in the list of exemptions in the SOP.
So he is obviously aware of the report of all the specialties, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
THE WITNESS: To that point, there's no way -- how would I know that? I can't tell what -- I can't tell what he looked at. I don't know where the 85 came from.
BY MR. CRAWFORD:
Q. All right. But, obviously, he -- you're criticizing his methodology here, right?
A. So I was responsible for compliance, and you always go to source documents. So because I can't understand

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which source documents he went to, it wasn't pointed out, that's kind of like -- that's what you learn, when you go into compliance, that your source documents are supposed to agree with your summaries.

So I'm missing something here. And that's what -- that's what I'm questioning.

And, I mean, I, maybe, could go through everything that he talked about, and I haven't had time to do that. But I think -- I think a lot of the concerns here is he really didn't delve into the details and ask the right people the right questions.

Because if you have a concern when you're auditing, you go to the next level. I don't believe Mr. Brennan did that, from looking just at his audit report.

Q. Well, I mean, he did go -- send this report to Tim Sheehan, which was his boss, you, Bob Bader, Mark

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Solomon.

So he did give the report and give some ability to respond, right?

That was the plan on the bottom here, it says, RA will issue a response audit report by 12/31.

That's you, right?

A. I wouldn't say this is a thorough initial audit report.

So when I would do audits -- or I should say oversee audits -- you know, I used to do GCP. So go to a hospital, you interview some people and you look at documents. But if something unusual occurs, you don't just stop there. Then you go -- you keep trying to, like, figure it out.

Because if my auditor came back and gave me a report that I didn't feel like they delved into what the rationale -- it could be a very innocent comment, and they could blow up something that makes it look worse than it is. I expect them to delve into the rationale

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and the reason why.

I didn't think that this report is that thorough and really supports his findings. And so if I was -- if I had an auditor, and, maybe a beginning auditor, I would mentor them and help them out.

But if this was somebody -- especially an internal company audit, where you have a lot more flexibility to go down the hall and talk to somebody, I think -- I think that this audit report is not very -- I'll get off my -- you know, I teach this stuff. So I just feel that this isn't a very thorough report.

Q. Do you know what he did afterwards with regard to this report in discussing it with company officials?

MR. DIAMANTATOS: Objection. Form. Calls for speculation. Foundation.

THE WITNESS: No, I don't.

BY MR. CRAWFORD:

Q. So how can you judge that he

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didn't -- he wasn't thorough on following up on what he found in the report?

MR. DIAMANTATOS: Objection. Form. Argumentative.

THE WITNESS: Because I -- as an example -- I mean, I didn't go through this thoroughly -- but he should have referenced the IMS data. And you said, okay, well, 85. But I don't see any -- I don't know where he's getting that from. It's not clear.

Something -- this is important, internal to the company, you should really -- it should be a roadmap to what the findings are.

So I don't think this is clear. And I don't want to -- you know, I don't want to throw him under the bus. I didn't have a long time to look at this. But you really have to lay it out. And that's what I would expect

from an auditor of mine.
BY MR. CRAWFORD:
Q. But Exhibit-14, this is the document -- the type of document you think he should have looked at, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
BY MR. CRAWFORD:
Q. That's what you're saying, he should have looked at the IMS -- this data right here, right?
A. Not just that, but for everything.
Like, so, for instance, you go through each -- and this is what I would expect from an auditor. I would go through each, like, the Walgreens, and then I would go and interpret, okay, well, it's only Walgreens -- what does he say -- Walgreens is the only chain represented.
Well, I would have gone to marketing and said, why is it -- you

know, I would have said, I investigated this and the others can't be represented, because there was -- you know, there was a practical reason why you can't. I don't think they were doing it anymore. I don't remember the details.
What I'm saying is you don't just -- you don't just identify issues. At this level, you try to -- you try to find out why, what you did. You don't just scratch the surface, in other words.
This is all -- there's a -- you know, if I went through this, there's a lot of benign issues here that if he just did a little more research, he'd find out, for instance, that -- I don't know, I'm making this up, that Eckerd no longer does this, for instance.
And I can't remember all the details. But there's a lot of very benign, rational reasons why things weren't done. And I don't think he went that far.
Q. Did you raise these

criticisms with Mr. Brennan at the time that he provided you with his audit report?
A. He didn't work for me. And I can't remember -- you know, we talked about all these things, and we went through the pieces and why -- and I think my memo addressed some of the issues.
Q. So look at Exhibit-12.
Did you raise any of these points with him in Exhibit-12, that he failed to do these things?
A. So this went to the highest levels of the company, and --
Q. Including Mr. Brennan, right?
A. Let me go through here.
Well, I mean, for instance, I mean, it wasn't -- you know, trying not to be personal. So, for instance, Number 3, the NDC Source Prescriber is used in place of IMS Xponent.
Well, I think, if he did a little more research, he would have found

out why we were doing that, that they were the same.
I'm not going to -- I hope you don't mind. I don't want to get into detail here. But that's just an example. So I'm not going to -- I don't want to -- I'm not going to say, Mr. Brennan should have done a more thorough -- I'm not going to put it that way. But that's kind of inferred.
Q. Right. But you agree that it's inconsistent with the RiskMAP, on the Walgreens example, that they're only using Walgreens and not the other four, right? It's just inconsistent with the RiskMAP --
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. -- right?
MR. DIAMANTATOS: Objection. Form. Foundation. Speculation. Asked and answered.
THE WITNESS: Right. And as I said previously, there are

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inconsistencies. And I told you that, you know, when we started at 10:00 or whatever, that a lot of it had to do -- because I said -- I said that operationally things evolved; however, that the -- you know, the function of what we were trying to do stayed the same.

So we weren't able to get Eckerd as a contractor, but we were able to get Walgreens, or something. But the intention was we were still doing what the FDA wanted, but we didn't have the ability to communicate a -- I should not say communicate a revision, but to revise it formally; they didn't approve it. But we did communicate to them those issues that we couldn't do this or we couldn't do that.

So why Mr. Brennan didn't do -- you know, if he -- if he -- that's just one example. But if

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he had dug a little further, we would say, yes, this is different, and this is the reason why, and we tried to communicate it to the FDA, we did communicate it to the FDA, but it's not yet approved. Something like that.

So that's why I'm saying -- I'm not saying there aren't differences. As I said from the very beginning, you'll find inconsistencies. But it wasn't because -- because we kept trying to communicate to the FDA and get it approved.

BY MR. CRAWFORD:

Q. So he should have dug deeper and found out that there was an excuse that you had --

A. That would be my interpretation.

MR. DIAMANTATOS: Objection. Objection. Mischaracterizes the witness's testimony. Form.

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Go ahead.

BY MR. CRAWFORD:

Q. And then it says that -- on his report, on Exhibit-10, he says, Items requiring follow up. The four listed pharmacy chains are not included, as required by Section 8.1.1. Section 8 further commits that if any of the four organizations are unable to participate, Cephalon will substitute another supplier. Only Walgreens is represented.

So he is not saying this is the final conclusion, but requires follow up, right?

MR. DIAMANTATOS: Objection. Form. Calls for speculation. Asked and answered.

BY MR. CRAWFORD:

Q. So he is opening up the possibility that there needs to be some kind of follow-up on this, right?

MR. DIAMANTATOS: Objection to form. Calls for speculation. Foundation. Asked and answered.

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THE WITNESS: I didn't read this whole document, but what he sent to the FDA doesn't look like -- I don't get the sense that he said, I did a really thorough investigation and, you know, these people are not doing what they're supposed to.

I think that there's holes that he's pointing out that -- or differences, but not explaining why. And it's creating more of an issue than was, in reality -- why the changes were there.

BY MR. CRAWFORD:

Q. But you said you didn't -- you didn't know what happened with him, with conversations afterwards, right?

A. No, I didn't.

Q. So possibly he did follow it up, right? But you don't know?

MR. DIAMANTATOS: Objection. Calls for speculation. Asked and answered.

BY MR. CRAWFORD:
Q. And then he was terminated, so he can't really do anything after he's terminated, right?
MR. DIAMANTATOS: Objection. Assumes facts. Asked and answered. The witness said she doesn't know how he left the company.
BY MR. CRAWFORD:
Q. He says he was terminated, right?
A. Yeah, I really -- I really -- I don't know. I really don't know.
Q. But you saw that he said in his letter to the FDA that he was terminated, right?
A. Here, yes.
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. All right. So Mr. Brennan's letter, Exhibit-17, is dated February

23rd, 2004, correct?
A. The FDA -- give me one second.
Q. Exhibit-17.
A. Give me one second here.
MR. DIAMANTATOS: Objection. Foundation.
THE WITNESS: Here we go. I'm gong to move -- give me one second. I'm going to move everything back --
BY MR. CRAWFORD:
Q. Take your time.
A. -- to the pile. Okay. I've got it in front of me.
Q. Just, the date is February of 2004, right?
MR. DIAMANTATOS: Objection. Foundation.
THE WITNESS: February 23rd.
BY MR. CRAWFORD:
Q. Yes.
A. Yes.
MR. CRAWFORD: I want to

mark the next document, 1692.
- - -
(Whereupon, Teva-Marchione Exhibit-18, TEVA_MDL_A_08242371-373, was marked for identification.)
- - -
MR. JENSEN: This is Exhibit-18.
BY MR. CRAWFORD:
Q. So this is an e-mail you wrote to Francine Del Ricci in June of -- June 7th, 2004, re: FDA contact report. FDA raises concerns about Actiq off-label use and diversion working document.doc -- and diversion.
There's an attachment, working document.doc?
A. So I actually forwarded it to her. I didn't write it to her. Just to be clear.
Q. Sure.
You wrote down below -- that's right. Your e-mail below is dated

June 4th, 2004, to a number of people, including high up in the company. You had mentioned Paul Blake, Ed Berg and others.
The subject is, FDA contact report, FDA raises concerns about Actiq off-label use and diversion.
Is that an e-mail that you wrote?
A. Yes, it is.
Q. And you write, Attached is a telephone contact report detailing the phone call that I received yesterday from Bob Rappaport, director of the division of anesthetic, critical care and addiction drug products. He expressed to me that high levels of FDA are very concerned about information that they have analyzed that reflect staggering off-label use and increasing reports of diversion, misuse and unintended pediatric use of Actiq. He is requesting that a Cephalon representative come to FDA within the next couple of months to

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discuss. He asked for a meeting package prior to this.

And this is what you reported.

Did you take that call from the FDA personally?

A. Yes, I did.

Q. And did he, in fact, report a staggering off-label use that he was aware of?

MR. DIAMANTATOS: Objection. Form.

THE WITNESS: I believe I tried to capture his words, so --

BY MR. CRAWFORD:

Q. And you agree, at this time you knew that the off-label use was high, you testified, right?

A. Yes.

Q. Did you know it was 90 percent, or thereabouts?

A. I didn't -- I didn't know the actual amount.

Q. So he asked for a meeting

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package prior to this.

Was that package sent to him?

A. Yes, it was.

Q. And was that the Exhibit-11 that you sent?

A. Yes.

Q. Let's go to the actual report you attach here. It's a regulatory telephone contact report from you.

And the discussion says that, Dr. Rappaport stated that the FDA is very concerned about reports of diversion and misuse of Actiq.

That's the first sentence.

Going to the second paragraph, it states, Dr. Rappaport stated that the agency's concern stems from analysis and reports that have come to the FDA's attention from review of their sources. He stated that rather than discussing specific details, the agency would like to meet with our

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company. One of the intentions of the risk management program was to limit the use of the product to the indication, and the reports that they are receiving regarding off-label use have them extremely concerned. Their sources reflect that many of the elements that the RiskMAP was intended to control, such as off-label use, especially, but also pediatric exposure, diversion and abuse, are increasing. These analyses are causing a real concern at high levels of the agency -- in the agency.

And, again, at the very end of the paragraph, the report states, He reiterated that the off-label use of the product is staggering.

So you agree here, I mean, just from the tenor of the call that you took from him, that they were very concerned at the FDA about the off-label use, right?

MR. DIAMANTATOS: Objection. Calls for speculation. Form.

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Go ahead.

THE WITNESS: And what triggered the call, which was stated here, was one case of diversion that made the -- that made the news. And that's what triggered the call. And the rest of the concerns he had there.

But it was -- it was that the -- what do you call it -- the API, whatever is on the wire, that there was a Philadelphia case, specifically, of diversion of Actiq is what triggered that call.

BY MR. CRAWFORD:

Q. So was it -- doesn't he say here that the concern for the staggering amount of off-label use is also a trigger of the call?

A. What was relayed to me, and what I put into -- let me see -- it says, In addition, please refer to conversation requesting the source of Actiq use of the Philadelphia diversion case.

So that may have been a call even before this one. There may have been two calls. But that's what started it.

And then -- I think then he -- then he discussed the off-label use also. I'm not negating it, I'm just saying that's what first triggered it.

Q. But one of the purposes of this particular call was the staggering off-label use that had come to the attention of the FDA and caused great concerns high up in the FDA, right?

MR. DIAMANTATOS: Objection. Form. Calls for speculation. Assumes facts.

BY MR. CRAWFORD:

Q. Is that what he told you?

A. Well, if you read the first sentence, it says -- he talks about the diversion of the product that -- a single incident of diversion that occurred in the beginning of the year in the Philadelphia area.

Q. That's what you explained to him, right --

A. No, no.

Q. -- not what he said to you?

A. No, no, that's what he initially called for.

I remember this very clearly. Because I heard about it and contacted DEA first, and I was getting ready to pick up the phone to FDA. And he called me before I had a chance to call him.

So that's how the call started. And then he said the rest of the information.

Q. Didn't the call start with him saying the FDA is very concerned about reports of diversion and misuse of Actiq? He said that there had been discussions at very high levels of the agency regarding several issues involving the use of our product.

You state, I explained that recent published articles have come to

the attention of the company regarding the diversion of the product that virtually stem from a single instance of -- incident of diversion that occurred in the beginning of the year in the Philadelphia area.

So you're -- so that's what you told him, right, about the Philadelphia incident? He did not tell --

A. No, he --

Q. -- you about it; you told him.

A. Maybe this was -- no, that's what he first called me about. That's what triggered this.

And then we talked -- again, I'm not denying that he said everything else. But that's what was the trigger, because it made the news and he was getting pressure from his management.

Q. Well, it seems like -- it seems like he was a little more concerned about the one -- a little bit more

concerned than just about the one incident of diversion in Philadelphia, right?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered. Argumentative.

THE WITNESS: As you -- as you can read here, the answer is yes, because I wrote this.

But I'm just saying how the -- the course of the conversation started with the Philadelphia incident.

BY MR. CRAWFORD:

Q. And then at the bottom of the page, that last paragraph, you say, He stated that he was very much involved with the drafting of our RiskMAP, RMP, that he knows this document very well and the agency is very concerned that the situation that occurred with OxyContin may happen again. He further stated that the RMP was designed to limit the use of

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the product to the indicated use and this does not seem to be working.
So he is telling you that the RiskMAP is not working, correct?
A. That's what he communicated in this -- as I captured it.
Q. So he -- it continues, Dr. Rappaport stated that he would like our company to come in for a meeting in a month or two to provide a review of the data on misuse, diversion, off-label use, deaths, pediatric exposure, addiction and abuse.
So that was the intent of the meeting that he wanted to call, right?
A. That's correct.
Q. And did that meeting, in fact, occur?
A. Yes, it did.
Q. And was that the mid July meeting of 2004?
A. Yes, it is.
Q. All right. You stated that,

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I concluded that our company is also concerned about the proper use of our product.
But we saw in that marketing plan that there was a reference to 90 percent off-label usage.
Did you see any concern in that marketing document about the off-label usage, or was it looked upon as a business opportunity by the company?
MR. DIAMANTATOS: Objection. Form. Entirely argumentative. Improper question. Foundation. Calls for speculation.
THE WITNESS: We actually relayed all this information to the FDA.
So I wanted to go in here to see what we talked about off label, so I can -- I think that's a nice way of --
MR. CRAWFORD: Your counsel can ask questions on that. I'm going to move to the next

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question.
THE WITNESS: Okay.
MR. DIAMANTATOS: I'm going to object to you interrupting her answering your question.
BY MR. CRAWFORD:
Q. All right. I'll withdraw the question.
MR. CRAWFORD: Let's mark the next exhibit, Doc 1689. That will be Exhibit-19.
- - -
(Whereupon, Teva-Marchione Exhibit-19, TEVA_MDL_A_03317918-921, was marked for identification.)
- - -
BY MR. CRAWFORD:
Q. This is an FDA letter. On the back page, they have the date, June 29th, 2004, from the FDA, including Mr. Rappaport, to Anesta Corporation, care of Cephalon, attention to your attention.
Do you recall receiving this

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letter from the FDA?
A. Not specifically. But I remember this meeting that went with it.
Q. Okay. So they're writing to you saying, We also refer to your telephone conversation with Dr. Rappaport on June 3, 2004 -- that was Exhibit-18 that we just looked at, right?
A. That's correct.
Q. -- in which he requested that Cephalon meet with the agency to present all of the available information on certain aspects of the Actiq product.
And he writes -- or the FDA writes, We are particularly concerned that Actiq be promoted strictly within its approved indication and only to the -- its appropriate target audience. We remind you that, per the indications and usage section of the Actiq package insert, Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the

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use of Schedule II opioids to treat cancer pain.

As you know, these restrictions are an important part of the risk management program for the drug, to discourage inappropriate and potentially dangerous misuse of the drug. We would like representatives promoting Actiq -- or for receiving -- I'm sorry.

We would like to know how your company targets physicians that are not oncologists for visits by sales representatives promoting Actiq.

So in this letter, he's requesting the type of information that he'd like to receive for the meeting, correct?

A. Right.

MR. DIAMANTATOS: Objection to form. Calls for speculation. Foundation.

BY MR. CRAWFORD:

Q. And he says, We would like to know the steps your company takes to

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ensure that there is no confusion about the appropriate indicated use of this drug. We are aware that your company disseminates unbranded disease awareness materials discussing breakthrough pain generally. Please inform us whether these materials are ever used in conjunction with promotion of Actiq, e.g., as part of a detail in which the sales rep also discussed Actiq, or disseminated with printed materials for Actiq.

Now, these requests for information from the FDA for the meeting, who, at your company, was in charge of putting this together to present to the FDA for the meeting?

A. I was.

Q. And where did you collect up this particular information that he's requesting?

A. From all over the company.

Q. And you're looking at Exhibit-11, correct?

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A. I am. I'm trying to see if there was a table of contents.

I mean, the RiskMAP is in there, a lot of IMS data, sales. Everything they asked for is included, including all the marketing information. The Dave Brennan audit report is in there. All of our safety information. There's tables on off-label use, misuse and abuse.

I don't see a table of contents. Oh, here it is.

Do you want me to go through each attachment and say where it came from? Is that -- I mean, I'm not quite sure what you'd like.

Q. I just wanted to know, generally, where did you get information to answer the question. I don't need to know specific. If you don't know generally, that's fine, we can skip ahead.

A. Generally, the safety group, the commercial group. We got the audit

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report from QA. We got all the promotion from marketing. Legal gave us some initiatives.

Q. So this letter, the July 12th letter that you wrote here, is this -- you wrote this letter, correct?

A. I'm sure there was a huge input from many people.

Q. All right. So there were drafts that went around, but you kind of spearheaded the effort to put it together, right?

A. Yes, that's correct.

Q. And if you could look at Page 8, the last paragraph, it states, Prescriber data obtained by Cephalon from IMS, NDC and Verispan do not provide any conclusive information as to the diagnosis of each patient at the physician or patient level. These data, as illustrated below, are available on Actiq prescribing by specialty and show the volume and distribution of prescribing of Actiq by specialists.

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Now, that first sentence is contradictory to what we saw in the marketing plan, where they actually could break it down by specialty from the IMS source data, correct?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: Again, I don't know where -- how that data was arrived at. They said IMS was source. But the FDA can also check with IMS.
So I believe what we've told them here was the truthful information we have, which did show -- you know, if you look through it, it does show the use in psychiatry -- you know, it does mirror much of the information that was in there.
BY MR. CRAWFORD:
Q. Right. But you're telling the FDA that IMS does not provide any conclusive information as to the

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diagnosis of each patient at the patient -- physician or patient level.
Is that what you're informing the FDA, right?
A. That's what I was told. And I really suggest that you talk to an IMS person to say what's the truth, because I don't --
Q. An IMS person within the company, right?
A. No. I mean, in all fairness, if you're investigating this, you can go to the IMS, and the date when this occurred, what was the ability of IMS to get this -- obtain this data. I don't know the answer. IMS could objectively tell you that information.
Q. Right. But the company obtained it somehow, because we saw it in the marketing plan, right?
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. Broke it down -- remember

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anesthesiology had back pain at 49 percent and other uses within that specialty, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
BY MR. CRAWFORD:
Q. Do you recall that document?
MR. DIAMANTATOS: Let me finish my objections for the record, please.
Objection. Form. Foundation. Calls for speculation.
THE WITNESS: I do recall it. I don't know exactly how they did it or how that information arrived.
I saw it. We read it together. That's all I can tell you.
BY MR. CRAWFORD:
Q. That's fine.
So somehow the company did

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get that data from somewhere, right?
MR. DIAMANTATOS: Objection. Form. Calls for speculation.
BY MR. CRAWFORD:
Q. Apparently, from the document.
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.
One second.
Go ahead.
THE WITNESS: I know as much as you do in this case.
BY MR. CRAWFORD:
Q. So you did reference a chart on the next page, and it breaks it down by specialty, the prescribing.
So it's PCP -- that's primary care providers, right?
A. Yes.
Q. And neuro is neurologists or neurology, right?
A. Again, I know as much as you. That's how I would interpret it.

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Q. And onc would be oncology?
A. That's how I'm interpreting it.
Q. Psych, psychology, right?
A. That's my interpretation.
Q. And PNAN, pain or anesthesiology, is that those areas generally?
A. You know, I don't know exactly. It sounds reasonable, from the way you said it.
Q. So you're reporting to the FDA here the usage by these five specialty groups, plus others; is that correct?
A. That -- yes.
Q. But when you do the 15 percent calculation, you're cutting it up much more when you try to analyze whether a particular specialty went above 15 percent, right?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: You know, I'd

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have to look at the algorithm and what was used. I really -- right now is probably not the best time for me to analyze this.
I don't know how this was arrived at versus the other. In the next page there is the quarterly distribution by specialty. So there's the percentages.
I mean, we were totally forthcoming to the agency on the off label and where the specialties were.
BY MR. CRAWFORD:
Q. Right. But you -- if, in fact, you had the data in your marketing plans in 2004 about the breakdown of usage within a specialty, like for anesthesiology pain, that isn't being forthcoming, then, if you tell them that IMS doesn't provide that data?
MR. DIAMANTATOS: Objection. Form. Argumentative.

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THE WITNESS: You know, all I can say is we're showing the FDA where the specialties are. I don't know all the details of how that was arrived at.
I don't know what else to say.
BY MR. CRAWFORD:
Q. We also saw from the marketing plan that PCPs, primary care providers, were above 20 percent as a specialty, right?
And that's what's reflected here, right?
A. Right. Okay. Yes.
Q. So if that was above 15 percent, why aren't -- since they are a nontargeted group, why weren't they reported in the report as being above the 15 percent threshold where some type of corrective action was taken pursuant to 9.1.2?
A. You're saying psychiatry?
Q. Right -- no, I'm talking

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about PCP, primary care providers.
A. Was that in the -- I was trying to think of the SOP.
Did they have PCPs in there?
Q. No, that was not -- as an untargeted -- as a targeted group, it wasn't and that's outside --
A. I don't know -- I don't know how they identified target -- I don't know all the -- all those categories. So I don't know how they add that up to be, this is a group or not.
And so I don't even know where the PCP, if it comes in one group. I'd have to look at the -- those tables with all that. So I don't know how that's -- how they summarized PCPs.
Q. Right. "They" meaning the sales department put that together?
A. The marketing research.
Q. Right. Marketing research. All right.
MR. CRAWFORD: Let's pull 627.

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MR. JENSEN: Exhibit-20.

- - -

(Whereupon, Teva-Marchione Exhibit-20, TEVA_MDL_A_01582360-377, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. These are the minutes of the meeting -- we marked Exhibit-20, TEVA_MDL_A_01582360.

These are the meetings of -- the minutes that the FDA sent to you of the July 14th meeting, correct?

A. Yes.

Q. And this is the one where you submitted Exhibit-11, the packet, to them, right?

A. Yes.

Q. So you attended this meeting, correct?

A. Yes, I did.

Q. All right. And the minutes -- the meeting objective of the

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FDA minutes state that, To get an update from the sponsor on information related to pediatric exposures, use, diversion, misuse, overdose, death and off-label use of Actiq and any noncompliance issues that the sponsor is aware of related to the risk management program implementation of Actiq.

So you agree that was the meeting objective as it's stated in that paragraph, right?

A. From the FDA perspective, yes.

Q. Okay. Was that the company's perspective, too?

MR. DIAMANTATOS: Objection. Form.

BY MR. CRAWFORD:

Q. If you know.

MR. DIAMANTATOS: Same objection. Foundation.

THE WITNESS: I mean, it was their meeting. So, usually, the person who calls the meeting has

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the objective.

BY MR. CRAWFORD:

Q. Fair enough. I understand. Thank you.

It says, The agency is concerned about the abuse and diversion of Actiq and would like to understand the steps Cephalon is taking to prevent abuse and implementation of the risk management program. Available data suggests considerable off-label use of Actiq and the agency would like to understand the steps Cephalon is taking to discourage such use and ensure that off-label promotion is not occurring.

If we go to the end there, Number 3, it says, The sponsor stated that they would like a meeting with DDMAC regarding concerns about the review process for draft promotional materials.

What is DDMAC?

A. It's the division of the FDA that is responsible for drug promotional review.

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Q. And it says, DDMAC expressed concerns about the information provided at this meeting and in the background materials regarding the sponsor's promotional practices as they relate to off-label use. And DDMAC recommended further discussions on this issue. DDMAC and the sponsor agreed to have a subsequent meeting to discuss these issues.

Post-meeting note. A meeting between representatives from DDMAC and Cephalon was held on August 30th, 2004.

Do you recall that meeting?

A. Yes, I do.

Q. And did you attend that meeting?

A. Yes, I did.

Q. All right. So let's mark the next exhibit, which is Document -- well, let's mark Document 1753.

- - -

(Whereupon, Teva-Marchione

Exhibit-21, TEVA_MDL_A_08245587-590, was marked for identification.)

- - -

MR. JENSEN: Exhibit-21.

MR. CRAWFORD: Give me one second here.

All right. I think we're missing the e-mail from this one. It's on the screen, but we have -- we don't have it printed. So we're going to have to get it, the e-mail part, printed and replaced here.

BY MR. CRAWFORD:

Q. But it's just a short e-mail. You're welcome to look at my copy of the e-mail here, if you'd like.

MR. CRAWFORD: Let's actually mark this. Here is the actual exhibit.

MR. DIAMANTATOS: Can you call out the Bates numbers, too, and make sure you give me the full

number?

MR. CRAWFORD: Right.

MR. DIAMANTATOS: Thank you.

MR. CRAWFORD: Let's do that. And I don't want to give you my boarding pass for United, so I'll take that off here.

So the Bates number there is TEVA_MDL_A_08245587.

Give that other document back, and we'll mark this one instead.

THE WITNESS: Sure.

MR. CRAWFORD: Thank you.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

BY MR. CRAWFORD:

Q. All right. There we go.

So this was an e-mail from you to Frances Smith, cc'ing yourself, draft DDMAC meeting minutes. Fran, I sent the attachment to Ed, Bob R., Andy,

Greg, Tracie and Victor. I'm not sure if it was received. Could you just check with Victor if he got it. If he did, the others did too. If he didn't, please call me.

I want to go to the attachment here, which are the draft meeting minutes from the August 30th meeting, right?

Did you prepare these?

A. I believe I did, based upon this.

Q. Do you know if these were ever finalized, from Cephalon's standpoint?

A. You know, I don't remember.

Q. Okay. All right. So you indicate that you attended the meeting with Ed Berg, the assistant general counsel, right?

A. That's correct.

Q. And Andy Pyfer was there as well, correct?

A. That's correct.

Q. And others from your company.

You write -- or what's written here is, Tom Abrams stated that after reviewing the July 4th -- the July 14th, 2004 meeting package -- are they referring here to the Exhibit-11 package?

A. That's my understanding.

Q. -- DDMAC has significant concerns about the promotion of Actiq. He stated that drug was approved under Subpart H, due to its significant safety concerns (i.e., it's dangerous and can kill opioid-naive patients and children at certain doses). FDA was concerned -- or was concerns, it says -- about the safety of the drug at the time of approval and it is concerned now. FDA wants to avoid the unsafe use of the product.

So do you recall, at the meeting, these concerns that DDMAC was raising about the promotion of Actiq?

A. Vaguely.

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Q. Abrams stated that he feels that Cephalon is not concerned about and encourages the off-label use of the product. He specifically mentioned that Cephalon did not seem concerned about the 15 percent cutoff of the inappropriate sales target.

Do you see that?

A. I do see that.

Q. Do you recall that being raised in the meeting?

A. I don't remember.

Q. Okay. And they're referring here, at least what's written in the draft minutes written by your company, to the 9.1.2, 15 percent cutoff, right?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.

THE WITNESS: That's how I would infer it. But, you know, I can't say 100 percent.

BY MR. CRAWFORD:

Q. All right. Down at the

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bottom, it says, After that introduction, Tom Abrams then provided more specific comments.

And then at the end of that paragraph, he says, His interpretation is that by sending letters for off-label use, it infers that Cephalon sales reps should be discouraging off-label use of the product. By going to prescribers who prescribe the product off label, Cephalon is reinforcing off-label promotion.

That is what is written here, at least in this draft form, of what transpired at the meeting, correct?

A. Yes.

Q. And then skipping down to the small paragraph two below that, After further discussions, Tom Abrams and Carol Barstow stated that they believe if we continue to promote and screen physicians, as we do currently, we are putting ourselves at risk. It was recommended that we review our sales training practices.

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So the FDA was concerned about the targeting of doctors that were outside of the intended targets, right?

MR. DIAMANTATOS: Objection to form. Speculation.

THE WITNESS: I mean, I think it's clear how it's written here.

BY MR. CRAWFORD:

Q. Do you recall at the meeting the FDA expressing concerns about how doctors were targeted for promotion?

A. I don't recall the details of the meeting. I'm just -- you know, I'm sure I captured what I thought down here.

Q. So when this was drafted, this was intended to try to capture, as best as possible, what transpired at the meeting, right?

A. That would be my interpretation.

Q. And then the last paragraph says, Tom Abrams concluded this part of

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the discussion by stating that FDA is looking at the total picture of sales and promotion of the product. He stated that our drug is under a lot of scrutiny beyond FDA. There have been complaints about the promotion of the product and that DDMAC is monitoring this very closely. He stated that they are prepared to take action beyond NOV letters and warning letters. He stated that it is the responsibility of the corporate compliance to investigate the sales training and materials.

So this is -- this seems like a rather harsh assessment of the promotional practices.

Did this raise any kind of concerns within the company, after this August 30th meeting?

MR. DIAMANTATOS: Objection. Form.

THE WITNESS: I mean, I can't remember actions afterwards. But, obviously, yes, it expressed

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concern.
BY MR. CRAWFORD:
Q. So he -- it sounds like -- like they're ready to take action beyond letters and warning letters, that's what happened.
And that means -- what type of actions does the FDA have the capability of taking in the regulatory framework beyond that?
MR. DIAMANTATOS: Objection. Form.
Go ahead.
THE WITNESS: They didn't take any action. They didn't give us a warning letter. They didn't give us an NOV letter. And they took no action.
BY MR. CRAWFORD:
Q. They took no action against you?
A. No.
Q. Or the company?
A. No.

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Q. It just died after this?
A. Yes.
Q. Okay. Last paragraph, last sentence, DDMAC will provide their minutes and Cephalon can review those and provide comments and clarification to those minutes.
So let's attach those minutes, which are 627.
- - -
(Whereupon, Teva-Marchione Exhibit-22, TEVA_MDL_A_01584978-986, was marked for identification.)
- - -
MR. CRAWFORD: Is that right? I'm sorry, 1691.
MR. JENSEN: Exhibit-22.
BY MR. CRAWFORD:
Q. So are these the -- we've marked here Exhibit-22, TEVA_MDL_A_01584978.
This is a letter from the FDA -- or DDMAC, rather, to you at

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Cephalon, correct?
A. Yes.
Q. And this appears to be the minutes of the August 30th meeting that the FDA is providing, right?
A. That's correct.
Q. And looking down here, under background, it says, Cephalon requested a follow-up meeting with DDMAC to discuss concerns regarding the review process for its promotional pieces. DDMAC agreed to meet with Cephalon and also stated that it would like to discuss various concerns DDMAC had regarding the promotion of Actiq, including concerns regarding information about Cephalon's promotion that was provided by Cephalon during the July 14th, 2004 joint division meeting and in Cephalon's briefing package for the July 14th, 2004 meeting.
So DDMAC was -- obviously, that meeting did not go that well on the 14th; they were pretty concerned about the off-label promotion in that meeting,

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right?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation. Argumentative.
THE WITNESS: I mean, I think you can read it. It wasn't -- they weren't giving us a pat on the back. But they also pre-cleared all our promotion pieces. So they saw everything that we sent them.
BY MR. CRAWFORD:
Q. What do you mean they "pre-cleared" it?
A. So under Subpart H, you have to send all of your promotion pieces to the FDA before you release it. So we did that. They gave us comments, and we incorporated. So they saw everything that we were promoting on.
Q. When you submitted the materials to the -- to DDMAC or the FDA?
A. No, DDMAC. DDMAC is a subset of FDA.

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Q. Did you have to get an affirmative approval back to use it, or was there, like, a 30-day period they could comment and then you could use it?
A. Yeah, within the 30 days -- I think it was 30 days, they would give us comments on the pieces.
Q. Right.
A. And we would review those comments and revise the pieces accordingly before we issued them.
Q. And what if you got no comment back at all, could you use the piece after 30 days?
A. We would always tell them that, but we always waited.
Q. Right. So you wouldn't even use a piece until you got something back from them, or were there instances where there's a time period they have to get back to you, and if they don't, you can use it?
A. I think --
MR. DIAMANTATOS: Objection

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to form.
Go ahead.
THE WITNESS: I think we would always wait for comments.
BY MR. CRAWFORD:
Q. The discussion points. DDMAC's concerns regarding off-label use of Actiq. The targeting criteria and lack of screening for physicians called upon by Cephalon sales force to promote. Actiq training and detailing practices, which inappropriately broaden the drug's labeled indication. The eliciting of and response of off-label inquiries regarding Actiq. Minimalizing the fatal risk of Actiq to children. And the promotional use of disease awareness materials that discuss conditions for which Actiq is not indicated to treat.
So those were DDMAC's concerns coming into the meeting, right?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

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THE WITNESS: That's what they wrote in here.
BY MR. CRAWFORD:
Q. At least reflected in the minutes?
A. Yes.
Q. Do you remember those concerns being raised in the meeting?
A. You know, in general.
Q. So the concerns regarding promotion here, it says, DDMAC expressed significant concerns about the increasing off-label use of Actiq, particularly in light of the risk management plan that is in effect for Actiq, which mandates that, among other things, the company act to prevent against improper patient selection. DDMAC reminded Cephalon that off-label promotion is illegal and, especially with a drug with a risk profile like Actiq, raises significant public health concerns. As discussed further below, DDMAC expressed concerns that Cephalon's training and detailing

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practices appear to encourage the off-label use of Actiq rather than discourage it.
So, again, was this a concern that DDMAC expressed in this meeting to Cephalon and its attendees?
A. I believe, I mean, like, being written in here, they expressed that.
Q. So these minutes, is there anything in these minutes -- and take your time to look at them if you want, we can go through it, is there anything in these minutes that seems inaccurate about what DDMAC had expressed to Cephalon during that meeting?
And go ahead and take your time if you need to look at that.
A. Again, this is, obviously, one-sided because they pre-cleared everything.
And the reason why we initially asked for that -- this meeting, which it said initially, was because they

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kept -- they kept reversing themselves on their promotional review. And I said, you're costing the company a significant -- a lot of money for your reversals.

So I asked for prospective meetings, on a quarterly basis, with them, so we could review together so we can get an understanding.

And that came out of that July -- I asked them for this in that July 4th meeting. And this was the follow-up.

So I think it says here that -- following the July -- Cephalon requested a follow-up meeting to discuss the concerns regarding the review process for its promotional pieces.

That's on the bottom, in the background.

So I asked for this meeting because I was concerned about how they kept reversing themselves. So I understand -- they probably had

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legitimate concerns, but the FDA pre-cleared all our promotion pieces.

So I feel like they were talking out both sides of their mouth, in a sense.

Q. So you said they reversed themselves.

Tell me what you mean by "they reversed themselves."

A. So in one -- in one piece they would say, you have to -- you know, you have to add this information, and then the next -- the next time we would add that information, we would put that in for another piece in pre-clearance with the information they wanted, and they would tell us to take it out.

So this went back and forth, every single piece. So, you know, they're not going to reflect in here their faults, necessarily. But, I mean, they pre-cleared everything, so I'm not quite sure why they were as surprised, if I should say, with the concerns. Because

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they -- they got to see all our pieces before we had them printed.

Q. Well, they're not talking -- the FDA -- DDMAC's concerns are on the second page at A.

And I don't really see much here about the promotional pieces, although I think they did have a concern about those at the meeting, correct?

MR. DIAMANTATOS: Objection. Form.

BY MR. CRAWFORD:

Q. They had a concern about promotional pieces at the meeting, is that what you're saying?

MR. DIAMANTATOS: Objection. Form. Calls for speculation.

THE WITNESS: I thought you were just reading to me where they were concerned about promotional -- I mean, I'd have to --

BY MR. CRAWFORD:

Q. I'm looking at discussion

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points, A. It says, DDMAC's concerns regarding -- the first is off-label use of Actiq.

They were more concerned about the use. Remember, the staggering use that the FDA brought up in the call, prior to the July 14th meeting.

So they are concerned about off-label use, which is, you know, not directly promotional materials, they were just concerned about the off-label use, right?

MR. DIAMANTATOS: Objection. Form. Calls for speculation.

THE WITNESS: I'm sorry, when you were reading something, it sounded very distinctly like they were concerned about the pieces.

BY MR. CRAWFORD:

Q. They may have been concerned about the pieces.

But they are -- also, that wasn't the whole subject of the meeting.

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They were concerned about the off-label use of Actiq, right?
A. Uh-huh.
Q. Do you agree?
A. Yes.
Q. Okay. And they were concerned about the targeting criteria used for targeting doctors with regard to Actiq, right?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: That's what it --
MR. DIAMANTATOS: Calls for speculation.
THE WITNESS: That's what it says here.
BY MR. CRAWFORD:
Q. Right. A promotional piece wouldn't necessarily clue them in to the targeting practices that raises these concerns, right?
MR. DIAMANTATOS: Objection to form. Calls for speculation.

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Foundation.
THE WITNESS: That's true. But the quarterly reports told -- inferred where the targeting was.
So we were very up front. We were very communicative. There was nothing that we were hiding. And this huge package, it was very specific about the off label and what we were targeting.
BY MR. CRAWFORD:
Q. Well, on off label, it didn't reveal that 50 percent, approximately, use among anesthesiologists was for back pain.
A. I mean, I can't remember the page --
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: I'd have to go through here. But we were pretty clear, I thought.
BY MR. CRAWFORD:
Q. I think you told them you

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couldn't break down what it was prescribed for within the specialty.
MR. DIAMANTATOS: Objection. Form. Mischaracterizes --
BY MR. CRAWFORD:
Q. Right. Remember on Page 8 --
MR. DIAMANTATOS: Objection. Form.
BY MR. CRAWFORD:
Q. -- of your letter?
MR. DIAMANTATOS: Objection. Form. Mischaracterizes testimony.
THE WITNESS: I'd have to go through here further. But I think we were pretty clear that there was significant off label, and I thought we gave percentages. It's been -- obviously, it's been a while since I --
BY MR. CRAWFORD:
Q. Why don't you take a look and find me the off-label disclosure in that letter?

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But this is in the July 12th letter you told them about it, right?
A. The meeting -- the meeting package?
Q. Yes.
A. Yes.
Q. You did not tell them about it in the quarterly reports, though? All the high off-label use, you didn't disclose that?
MR. DIAMANTATOS: Objection. Form. Vague. Asked and answered.
THE WITNESS: We complied with everything they asked for in the quarterlies. And there's -- in there we talk about off-label letters and everything.
Again, I'd have to -- it's been a while for the specifics. But we even showed a graph, I thought.
Actiq off-label counts and patient exposure. It does show a diagram, this is off-label counts

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versus patient exposure. This is a very thick document.

But we were very forthcoming. Counts, letters, patients' exposure.

It would take me forever to go through this.

BY MR. CRAWFORD:

Q. Well, why don't you grab Exhibit-9, which is your quarterly report, and show me where you're disclosing the level of off-label use in that report?

MR. DIAMANTATOS: Are you withdrawing the question with regard to Exhibit-11, or are you going to give her an opportunity to find what you asked her to find?

MR. CRAWFORD: I thought she said she couldn't find it.

MR. DIAMANTATOS: That's not what she said. She said it would take her time to find it.

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MR. CRAWFORD: I'll withdraw it.

MR. DIAMANTATOS: Why don't you note for the record how large Exhibit-11 is, by listing the Bates stamp? That's something you failed to do in comparison to what the other exhibits are.

MR. CRAWFORD: I only raised it because she said, counsel, that we told them about all the off-label use in the report.

So I asked her -- it is a large report, I agree. So I'll withdraw the question.

BY MR. CRAWFORD:

Q. Let's go to your quarterly report at Exhibit-9.

The document will speak for itself, whatever is disclosed in there is disclosed in there.

So let's go to Exhibit-9. And if you could -- was Cephalon forthcoming in this report about the

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extent of off-label use of Actiq?

MR. DIAMANTATOS: Objection. Form. Argumentative. Asked and answered. The document will speak for itself.

MR. CRAWFORD: I wanted her view that if it is --

MR. DIAMANTATOS: You didn't want it on Exhibit-11.

MR. CRAWFORD: I got it already. I just had her point it out.

THE WITNESS: So there's no -- no specific section that says what's your off-label use. We had a report on all these other -- so, I mean, we talked about all the off-label letters we got when we heard about it.

There isn't anything in here to specifically ask, what's your percent of off label?

BY MR. CRAWFORD:

Q. Well, okay. On Page 11,

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9.1, there's a section called, Off-label usage, right?

A. Let me see. 9.1.

I'm sorry, I'm looking at Exhibit-7.

MR. DIAMANTATOS: Exhibit-9.

BY MR. CRAWFORD:

Q. Exhibit-9, I'm sorry.

A. This is the RiskMAP.

I'm sorry, what page was it?

Q. Page 11. There's a section on off-label usage, and there's no disclosures in there about the extent of the off-label usage or anything being done.

A. So what it tells you that we need to do is, initial instance of off label -- it doesn't ask for numbers. It says we need to send a letter from our global product safety, which we did.

Q. And then 9.1.2 is missing.

That section is missing, right?

MR. DIAMANTATOS: Objection.

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Form.
THE WITNESS: And that's about the percentage. That was about the 15 percent.
So that's about the targeting. So that's not necessarily about how much -- you know, like, it doesn't say, give your percentage of off label.
BY MR. CRAWFORD:
Q. Let's go back to Exhibit-22.
So I think my question was here, I mean, these are minutes from the FDA of DDMAC's concerns that are outlined in Points 1, 2, 3 and 4 through 6. They express concerns here.
Were these concerns -- does this accurately reflect, in your view, the concerns that DDMAC raised at this meeting that you attended?
A. I'm going to have to read it.
Q. Sure.
A. Give me a couple of minutes.

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Q. Yes.
A. You started with 2, did you?
Q. Yeah. And actually I can go through the points that I -- that I'm really concerned about or want to raise with regard to whether they raise these concerns.
A. Okay.
Q. So 2 -- I think we went through 1.
2, DDMAC expressed concerns that, as indicated by Cephalon's briefing package for and presentation at the July 14th, 2004 meeting, the company targets physicians for Actiq promotion purely based on the number of opioid prescriptions they write, and the company is making no effort to screen these targeted physicians to determine whether they treat cancer patients and, thus, would be appropriate to be detailed on Actiq, given its limited indications, i.e., management of breakthrough cancer pain, in patients with malignancies who

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are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
Again, was that -- was this type of targeting concern raised at the meeting, that you recall?
MR. DIAMANTATOS: Objection. Form. Assumes facts.
THE WITNESS: I believe it was. But I'm not seeing -- I'm just trying to see -- we obviously responded to in the meeting.
BY MR. CRAWFORD:
Q. Right. But they give you --
A. The company takes the law applying the -- very seriously. Cephalon confirms that it does target physicians in various specialties by their opioid prescribing practices, regardless of whether they treat cancer patients or cancer pain. Specifically, physicians who write at least 24 opioid prescriptions in six months are targeted for a sales call by Cephalon sales

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representative. The company believes that it's a good idea to call on physicians who do not treat breakthrough cancer pain, based on belief that such calls can encourage these physicians to treat these conditions, should they see it in their practice. The company also stated its belief that a physician did not need to routinely see cancer patients to be an appropriate target for an Actiq sales call. Cephalon also confirmed that its sales representatives will make repeated calls to target physicians who are not using Actiq for the treatment of breakthrough cancer pain. Cephalon also indicated its belief that in addition to communications from its medical department, sending its sales representatives to call on physicians who are using Actiq off label was an effective way of communicating important risk information to these physicians and did not encourage off-label use, though they would consider DDMAC's comments on

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the issue.
Cephalon also noted it's belief that the RiskMAP, RMP, does not require the company to discourage off-label use of Actiq. While noting that it does not promote Actiq off label, Cephalon stated its belief that pain in general is an underrated medical need and that Actiq can be used safely and effectively for other uses than breakthrough cancer pain. The company will be pursuing a broadened indication for the drug.
Q. And doesn't DDMAC address that argument in the paragraph above?
They state here, Actiq's briefing package, at Page 598, in comments made by Cephalon at the July 14th meeting, indicate that Cephalon sales representatives are calling on physicians who are not treating BTCP, breakthrough cancer pain, and who are not prescribing Actiq already. This is especially concerning, as many of the

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targeted specialty areas, such as physical medicine specialists, do not routinely treat cancer patients. There does not appear to be any reason -- let me back up.
The physical medicine specialties were -- was a specialty group that was designated as a targeted group, and so, therefore, was not being monitored for the 15 percent or for the off-label promotion in the SOPs, right?
A. You know, I can't remember exactly. But the rationale for why they were doing what -- what they -- what were targeted to do is in this second paragraph.
So I believe -- I'm not denying that DDMAC feels that way. I think we have -- I think, Cephalon had a very logical rationale for why we promoted, to make sure it was safe.
And subsequently, we never got a warning letter. We never got an NOV. And they never took the approval

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away. So I don't know how one can interpret that, other than, you know, we were -- we expressed what our issues were, and, you know, it's kind of on either side.
And, you know, I think that -- you know, I think that paragraph speaks for itself.
Q. Didn't Cephalon pay a $50 million fine, criminal fine, for promoting Actiq and other drugs off label during this period?
MR. DIAMANTATOS: Objection. Form. Foundation.
Go ahead and answer the question.
THE WITNESS: To be honest, I thought it was -- I thought it was for Provigil. I didn't know if Actiq was part of the --
BY MR. CRAWFORD:
Q. It was Gabitril, Provigil and Actiq.
A. And that was not -- I mean,

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that was not -- FDA did -- again, that's what my hat is, the regulatory FDA hat, I have never heard anything back from the FDA, per se, that we were -- after that, that they held anything up or NOVs or anything.
Q. So you never heard that Cephalon had pleaded guilty to off-label marketing of Actiq and Provigil and Gabitril?
MR. DIAMANTATOS: Objection to form. That mischaracterizes the witness's answer.
Go ahead and answer.
THE WITNESS: I'm talking -- I'm -- my responsibility was my communications with the FDA, and how they interpreted.
We never had the product withdrawn or an NOV or warning letter from the FDA. So I'm just -- and I hear what you're saying. I'm not trying to deny it. I'm just saying, this was my

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focus.
BY MR. CRAWFORD:
Q. Right. And I'm just trying to understand if you had ever heard that Actiq was part of the -- Actiq off-label marketing by Cephalon was part of the guilty plea that they entered in 2008?
A. You know, my recollection, I thought it was just Provigil. I really -- I'm not trying to be --
Q. I know.
But you don't remember it being Actiq?
A. No, I actually did not. To be honest, I didn't.
Q. Fair enough.
They do -- and this is in response to the paragraph you read. They say, There does not appear to be any reason for these sales calls to be, other than to promote Actiq outside its labeled indication. And the fact that off-label prescriptions have increased in such specialty areas seems to add validity to

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this conclusion.
So you don't deny that there's staggering off-label use of the product at this time?
MR. DIAMANTATOS: Objection. Form. Argumentative.
THE WITNESS: I --
MR. DIAMANTATOS: Foundation.
Go ahead.
THE WITNESS: I will agree there was off-label use at the time, yes.
BY MR. CRAWFORD:
Q. But would you agree it was staggering?
MR. DIAMANTATOS: Objection. Form.
Go ahead.
THE WITNESS: How does one define that? I don't know. I'm being open, I'm saying, yes, I agree there was off-label use.
BY MR. CRAWFORD:

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Q. In your view, would 90 percent off-label use be staggering?
MR. DIAMANTATOS: Objection to form. Assumes facts. Argumentative. Asked and answered.
THE WITNESS: I don't know if I would -- I probably -- staggering.
I don't know. I guess -- it's definitely high, but there's a lot of people -- I don't know.
Yes, it's a high level.
BY MR. CRAWFORD:
Q. But the intent of the RiskMAP was to try to prevent off-label prescribing, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.
THE WITNESS: That was one of the three intentions of the RiskMAP.
BY MR. CRAWFORD:

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Q. And then, and this is more specific to what you read, In addition, DDMAC expressed concerns regarding Cephalon's stated reason at the July 14th meeting for sending sales representatives to call upon physicians who were clearly using Actiq off label, namely, to provide risk information to help ensure safe use of the drug. While DDMAC acknowledged how important it is that these physicians receive information from Cephalon regarding the serious risks associated with using this drug, as per the RiskMAP, DDMAC questioned whether having a promotional arm of the company, the sales force, repeatedly call on these physicians was the most effective way of communicating risk information and whether it would not also potentially encourage -- encourage rather than discourage the off-label uses, which would violate the principles of the RiskMAP.
So DDMAC clearly disagreed

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with your rationale of sending these sales representatives -- or the company's rationale of sending these sales representatives to doctors who, in general, didn't treat cancer patients, to try to talk to them about risk information. They thought it should come from a nonpromotional arm.

Do you agree that that was the position they took at the meeting?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Argumentative.

BY MR. CRAWFORD:

Q. You attended this meeting, right?

A. Right.

I understand -- I understand the rationale, yes.

Q. Okay. And then, 3, DDMAC expressed concern that Cephalon, as indicated in the briefing package for the July 14th, 2004 meeting, see Page 191, and in its presentation at the meeting,

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is instructing its sales force to open sales calls in a manner that fails to focus on Actiq's limited indication and instead focuses on the physician's treatment of breakthrough pain in general, thus inappropriately broadening physicians' perceptions of the drug's use to the treatment of all forms of BTP rather than BTCP in the indicated populations.

So, again, was this another concern that DDMAC expressed in the meeting?

MR. DIAMANTATOS: Objection to form and foundation. Calls for speculation.

THE WITNESS: I mean, just by -- I mean, this sounds correct. It's in the minutes.

We did not object -- we added a document in the file to these minutes, if I can remember. And I can't remember what they -- I don't know if you can find that.

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But -- so we did have some clarifications to these minutes after the fact. So I just don't remember the details.

BY MR. CRAWFORD:

Q. And then just skipping ahead to 6, it says, DDMAC expressed questions and concerns regarding how Cephalon's sales force is using disease awareness materials that discuss broad conditions, such as BTP, that would go beyond Actiq's indicated use.

Is that, again, another concern they expressed at this meeting?

MR. DIAMANTATOS: Objection. Form.

THE WITNESS: Again, I don't remember specifically. But I'm deducing, because it's written here.

BY MR. CRAWFORD:

Q. So, in summary -- and there are other points, but in summary, they state, DDMAC summarized that it is

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concerned -- this is on the last page.

A. Okay. The very last?

Q. Yes, very last page under summary.

A. Okay.

Q. I just want to look at that first paragraph there under summary.

A. Where it says, DDMAC summarized? That one?

Q. Yes.

DDMAC summarized that it is concerned about the promotion of Actiq and is monitoring this promotion very closely.

So DDMAC was, in fact, intending to monitor this? It wasn't going to just drop it, right?

MR. DIAMANTATOS: Objection. Calls for speculation. Form.

BY MR. CRAWFORD:

Q. Is that what they conveyed at the meeting?

A. That's what they conveyed.

By default, they pre-cleared

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all the promotional pieces. So by default, they were doing that anyway.
Q. So after this time, do you remember DDMAC doing anything about this, or did it just drop?
MR. DIAMANTATOS: Objection. Form.
THE WITNESS: We never got any -- anything else after this.
Again, the only other communication was I sent, I thought, a clarifying letter, to the best of my knowledge. I can't -- maybe I'm misinterpreting because there were so many meetings, but -- so I think we expressed some clarification on our part.
But we never got an NOV or a warning letter after this.
BY MR. CRAWFORD:
Q. Okay. It does say, DDMAC also noted that FDA is prepared to take whatever action is necessary to address

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any violations and ensure that Cephalon complies with the law and that the public health is protected. Cephalon should also be aware that DDMAC has received complaints about its promotion, and that it is under scrutiny by others who are concerned about the potential for harm to the public health from inappropriate use of Actiq. Cephalon is strongly advised to take whatever steps are necessary to ensure that it is in compliance with the law.
So they wanted you to take steps to comply with the law.
Did you have to wait for them to keep pushing you or prompting you to do it, or would you take steps -- was the company going to take steps to comply with the law?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Argumentative.
Go ahead and answer.
THE WITNESS: So it's an

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interpretation. We never got anything that said that we weren't complying with the law from the FDA.
BY MR. CRAWFORD:
Q. All right.
MR. CRAWFORD: Let's mark the next few exhibits.
MR. DIAMANTATOS: If you're moving on to another exhibit, maybe it's time to take a break. We've been at it almost an hour and-a-half.
MR. CRAWFORD: We can do that.
VIDEO TECHNICIAN: Going off the record at 4:03 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: Back on the record at 4:17 p.m.
BY MR. CRAWFORD:

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Q. We marked three of the next exhibits, 23, 24 and 25.
- - -
(Whereupon, Teva-Marchione Exhibit-23, TEVA_MDL_A_07424105-109, was marked for identification.)
- - -
(Whereupon, Teva-Marchione Exhibit-24, TEVA_MDL_A_00267691-694, was marked for identification.)
- - -
(Whereupon, Teva-Marchione Exhibit-25, TEVA_MDL_A_01583546-550, was marked for identification.)
- - -
THE WITNESS: Thank you.
BY MR. CRAWFORD:
Q. 23 --
MR. DIAMANTATOS: Sorry, I think I have -- 24 and 25.
THE WITNESS: Thank you.

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BY MR. CRAWFORD:
Q. Exhibit-23, if you look at the last page, it's a fax cover page, is a September 29th, 2004 fax from DDMAC to Tracie Parker.
That was your person who reported to you, correct?
A. That's correct.
Q. Okay. And it's TEVA_MDL_A_07424105.
And then we've also marked as Exhibit-24 a letter from DDMAC to Ms. Parker there at Cephalon regulatory affairs. That's dated November 24, 2004.
And then Exhibit-25 is a fax, again, from DDMAC to you, Ms. Marchione, dated November 29th, 2005.
So these are three DDMAC letters written with regard to the submission of promotional materials Cephalon made to DDMAC regarding Actiq, correct?
A. To clarify, it's draft promotion. This was part of the

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pre-clearance process.
Q. Right. So DDMAC was getting back to you and providing criticisms of those materials and asking Cephalon to correct them, correct?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: Or to revise them.
Again, it wasn't -- these pieces weren't out in the public at all. These were just draft that went to the FDA for pre-clearance.
BY MR. CRAWFORD:
Q. Right. So this -- all three letters come after the August 30th meeting, following up with your meeting with DDMAC, where DDMAC was coming to you explaining why these materials you were proposing using for Actiq were improper, right?
A. Right. But we have -- just to be clear, we have these throughout the

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review process, before and after. Every time we sent any piece that ever went out, we got one of these letters.
Q. Right. But these three are pointing out problems with these pieces, aren't they?
A. There --
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: Problems, maybe, is the wrong word.
But this is the whole point that I was saying, is we would get these types of -- so every piece we sent, we would get a letter like this. And then, like, the next piece would then reverse it.
So these are -- this is just a routine type of review. And they always gave us comments, one way or the other. So this wasn't something that was out in the market that we were distributing.

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BY MR. CRAWFORD:
Q. Right. So each of these letters they state, up near the beginning -- so let's take Exhibit-23, as an example, they state, Since many claims and representations are similar or closely related, DDMAC's comments on a particular claim or representation apply to similar claims or representations in these and future promotional materials for Actiq.
Right? So they were trying to teach you how to -- how to properly prepare these materials, right?
MR. DIAMANTATOS: Objection to form. Speculation.
Go ahead.
THE WITNESS: So we're -- not teaching, but they're saying -- this was my concern with the agency, was so they say, okay, for the future, you have to do this.
Then we would get another

piece that would completely reverse it, and say in the future you have to change these pieces. It was costing us extremely -- you know, a large sum of money, because every time they kept reversing their positions.

So these are their judgments on draft pieces. When we would get these comments, we would then take our draft, revise them, based upon -- to make sure they were in compliance. And then that would be, then, the final piece.

BY MR. CRAWFORD:

Q. Correct.

So they're telling you what's wrong with the pieces, and you're going back and correcting them and re-submitting them?

A. That correct.

Q. And their intent is, in telling you this, that you should apply their comments to future promotional

materials regarding Actiq, right?

A. That's correct.

MR. DIAMANTATOS: Objection to form. Speculation.

BY MR. CRAWFORD:

Q. They say that in the first paragraph here, up above, Since many claims and representations are similar or closely related, DDMAC's comments on a particular claim or representation apply to similar claims or representations in these and future promotional materials for Actiq.

Right?

A. That's correct.

Q. And that's -- they state that again on Exhibit-24, right below the bullet points, right?

A. Yes.

Q. And then Exhibit-25, they're stating it again in that first -- the last sentence of that paragraph, underneath the bullet points, right?

A. That's correct.

Q. So this first letter, dated September 29th, that comes about a month after -- less than a month after your meeting with them, right?

A. I guess --

Q. August 30th meeting, right?

A. Okay. Yep.

Q. So they are giving you -- they're following up on that meeting and telling you what's -- what the problems are with your promotional materials, right?

MR. DIAMANTATOS: Objection to form. Speculation.

THE WITNESS: No.

MR. DIAMANTATOS: Argumentative.

THE WITNESS: That's not what's happening.

So this started -- this is just a normal review process. It's nothing to do, necessarily, with that meeting.

We had this review process

going on for the whole -- for the whole lifecycle of Actiq. And we will get these kind of comments -- even though the timing may be such, but these were -- this is a common -- this is how they write these letters. It's just giving you the perspective of how they want these draft pieces to be revised.

So this is -- we have maybe -- probably 100 of these, or something. So every time we went to put a promotion piece out, we'd have to get it pre-cleared.

BY MR. CRAWFORD:

Q. Okay. So this Exhibit-23, they talk about unsubstantiated comparative claims, lack of important contextual information, misleading presentation of information, overstatement of efficacy.

Are these common comments made in the past about -- prior to this

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letter, about Actiq promotional materials or draft ones that were provided to them?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: This is how they -- this is how they kind of talk when they reviewed the documents. So it's -- it's, you know, this is how they tell you to change things.
And they always have to -- they always have to support it in context of the regulations. And so they'll say, you know, it's overstatement or whatever. So they're trying to have you change something.
But this is what pre-clearance is all about. And Fentora was breakthrough -- our subsequent approved product that the FDA didn't have any problem, we had the same types of pieces.
This is just -- this is a

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reflection of the review process of promotional pieces, in general, for pre-clearance.
And it's only under Subpart H do you get this. When you're not under Subpart H, you kind of -- you just get it out there, and then when's you get an NOV or warning letter.
But this is the normal kind of comments that you get back. And I've had other Subpart H products, and they sound just like this.
BY MR. CRAWFORD:
Q. For non-Subpart H products, my understanding, in the pharmaceutical regulatory world, that you have to submit your promotional pieces to the FDA, there's just a 30-day period for the FDA to comment or reject it, right?
A. So it's actually -- no, that's not the case.
So for non-Subpart H, it's a

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filing process. And they don't even look at it unless something invokes them to have a problem.
So I think in a reference to, you know, the meeting minutes you had from Abrams, tongue-in-cheek, other companies will complain about -- this is very common now -- there's actually whole groups within drug companies that look at competitor's promotion and send complaint documents about what they're doing.
So, like, the reference that you read to me from Abrams, he says, well, we get complaints. Well, it could also be that. I mean, there's -- the big pharma all have these -- you know, they're kind of review people for other people's promotion.
So that's -- that's regular pieces.
Under Subpart H, you cannot -- as I said before, they approximate -- they tell you to approximate, like, 30 to 45 days. And

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it's not under a PDUFA time frame, so you're kind of at the mercy of them of when you can get your responses back.
So for every single piece that has ever been produced, for both Fentora and Actiq, we have documents that look just like this. And that was my -- you know, not to belabor, but that was my frustration with the agency and why I asked for that meeting.
Because -- so you'll get this and they all say, just the way you pointed out that, okay, future ones have to do this. So we go ahead and pull back and change everything because of this.
And then we'll get the next one that will say not to do that, with future pieces to do that. And that's what my concern with the agency was that, and that's why I said, can we prospectively have a quarterly meeting? So we don't have to keep doing this. And they said no, we can't do that.
So I wanted to be more

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proactive with the agency and make sure that, you know, I thought, suppose we just had a dialogue as opposed to writing back and forth, we'd have a lot more productive pieces and more in line with their thinking. But they did not have the manpower for that.

Q. Well, they're trying to communicate in these letters to you what they feel is inappropriate about the piece, right?

MR. DIAMANTATOS: Objection to form. Calls or for speculation.

THE WITNESS: Yes, this is a recommendation to change. Yes.

BY MR. CRAWFORD:

Q. And then so, for instance, on Exhibit-24, this is the November 24th, 2004 letter, they are saying one of your Actiq montage journal ads are -- have misleading presentation of information. They have overstatement of efficacy. Minimization of risk. With regard to the

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Actiq detail aid, it omits important risk information. Overstates efficacy.

So they're giving you guidance here, in these letters, about what they feel is appropriate, or, actually, what is inappropriate for these ads, right?

A. That's --

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: Yes, that's what pre-clearance is all about.

BY MR. CRAWFORD:

Q. And so, then again, in Exhibit-25, they're talking about overstatement of efficacy again in your promotional pieces, misleading claims.

So they are giving you feedback, aren't they, in these letters?

A. They are.

And I'm just saying, this terminology, when you see, overstatement of efficacy, that's -- I want to say

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that's FDA-ese, that's how they talk. I mean, every piece says that.

And I've had promotion pieces pre-cleared, you know, for other things. And that's kind of the dialogue.

Q. Don't you think Actiq had a problem with overpromotion and promoting off label? Wasn't that a big problem?

MR. DIAMANTATOS: Objection to form.

BY MR. CRAWFORD:

Q. At least in DDMAC's view?

MR. DIAMANTATOS: Objection to form. Calls for speculation.

THE WITNESS: So after they gave us guidance, we would revise the piece accordingly, according to what they said. And we never got an NOV or warning letter after.

So we would take this information, we revise the piece, we produce the piece. We may have gotten an NOV because of the --

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maybe, one -- there were like -- it went to, like, 15 companies because it was an electronic issue. And that was -- that was more of an electronic issue.

So when you did Actiq, it cut off the adverse events. And there were -- and we got, the bucket of 15 other companies, all having the same issue. And it was electronic information.

But other than that, we never had a single NOV on this.

BY MR. CRAWFORD:

Q. All right. I'm going to mark the next exhibit.

MR. JENSEN: 26.

- - -

(Whereupon, Teva-Marchione Exhibit-26, TEVA_MDL_A_01583458-460, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. We marked here a June 25th, 2005 letter from Mr. Rappaport, of the FDA, to your attention. It's TEVA_MDL_A_01583458.

The document stated it's concerning your new drug application, dated November 22nd, 2004 -- or supplemental new drug application. The supplemental new drug application proposes changes to the risk management program, it states.

So this -- apparently, you had submitted, for the company, proposed changes to the Actiq risk management plan. And this, their statement here, they say, We have completed our review and find the information presented is inadequate and the supplemental application is not approvable.

Do you recall receiving this letter?

A. I actually thought we had one response back, out of all our correspondence. So it kind of was in the

back of my head that we got one letter.

Q. So they rejected the proposed changes you had made to the RiskMAP and submitted to them as a supplemental application, as you're required to do under the RiskMAP, right?

A. Correct.

Q. And so they say, underneath, According to -- they say that, Deficiencies are summarized as follows. Number 1, according to patient surveys, only 25 of patients are now receiving welcome kits. The method of distribution of the kits has changed from the original launch method of receiving them directly from the prescriber to either receiving them from the prescriber or via a toll-free number. At the same time, accidental exposures in children are increasing.

It is instructing you to, Evaluate whether the current method of distribution of the welcome kit provides an effective means for patients to obtain

the kit. And if not, propose a strategy for improvement.

So that was one reason they rejected it, right, or found it not approvable?

MR. DIAMANTATOS: Objection to form. Calls for speculation.

BY MR. CRAWFORD:

Q. Is that right?

A. As you read it.

Q. Okay. And then it says, 2, The off-label use of Actiq and the number of accidental pediatric exposures to Actiq have been increasing, yet you propose an expansion of the target prescribers. Explain and justify the proposed change, in wording, regarding prescribers from oncologists and pain specialists to physicians with special training.

That was another thing they wanted you to go back to explain, right?

A. That's what it says here.

Q. And then, 3, You propose a

decrease in the surveillance of off-label use of Actiq, in the face of increasing off-label use by prescribers. Justify the proposal for decreased monitoring of off-label use of Actiq and outline effective intervention to discourage it.

So they have rejected here, at least for these reasons stated, in your view, the proposed Actiq changes to the RiskMAP, right?

A. That's what it says here.

Q. And do you know if, at any time prior to -- do you know if, at any time, whether the FDA approved any changes to the RiskMAP, after this date?

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: I don't remember.

BY MR. CRAWFORD:

Q. You don't remember if they did?

A. Normally, the next step is

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that we would then send a response. I don't remember what happened.
And it was near the -- it was near the launch of Fentora, so I don't know the timing.
Q. Okay. Fentora, I think we established, was 2006, right?
A. Yes.
Q. All right.
MR. CRAWFORD: Let's mark the next exhibit. This will be 99. And let's mark 533, and we'll just give them both.
- - -
(Whereupon, Teva-Marchione Exhibit-27, U.S. Department of Justice - Pharmaceutical Company Cephalon to Pay $425 Million For Off-Label Drug Marketing, was marked for identification.)
- - -
(Whereupon, Teva-Marchione Exhibit-28, Government's Memorandum for Entry of Plea and

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Sentencing, was marked for identification.)
- - -
MR. JENSEN: 27 and 28.
BY MR. CRAWFORD:
Q. Okay. We marked --
MR. CRAWFORD: I'll wait for the witness to get it here.
BY MR. CRAWFORD:
Q. All right. We marked here a U.S. Department of Justice, Eastern District of Pennsylvania, press release, dated September 29th, 2008.
And then -- which is Exhibit-27. And it's entitled, Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing.
It states here -- first of all, let me ask you, do you have any recollection, during this time period, of Cephalon paying -- being held to pay $425 million for off-label drug marketing during this time period?

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A. I mean, I remember the CIA and -- and there was a lawsuit. I kept thinking it was predominantly Provigil.
Q. It says here, The United States Attorney General Michael B. Mukasey and Acting United States Attorney Lori Magid today announced the filing of a criminal information against, and a civil settlement with, the pharmaceutical company Cephalon, headquartered in West Chester, PA, for the off-label marketing of three of its drugs. Magid, in today's announcement, were joined by FDA Special Agent-in-Charge Kim Rice -- and others here that they list in the press release.
And it says, in the next paragraph, The information alleges that from approximately January 2001 through at least 2006, Cephalon promoted the drugs Actiq, Gabitril and Provigil for uses other than what the federal Food and Drug Administration approved. The company is charged with one count of distribution of misbranded drugs,

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inadequate directions of use, a misdemeanor offense.
Do you, looking at that, recall now that this applied to Actiq?
A. Well, it says it here, so.
Q. At the time, you did not know it was, up until today?
A. You know, I really don't remember. I really don't remember.
Q. So was there any discussion in the company about paying this fine and trying to --
A. So we were --
Q. -- do something about this?
MR. DIAMANTATOS: Objection to form. And objection to privilege, to the extent it includes conversations with in-house counsel about this particular lawsuit.
I just want to clarify that your question isn't calling for those types of communications.
BY MR. CRAWFORD:

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Q. Do you recall discussing this within the company, this criminal plea and fine?
A. I never saw this particular document. I understand, you know, the CIA, we signed a review of that and, you know, whatever -- I could not remember if Actiq was in there.
Reviewing this now, it talks about -- and I've reviewed every single promotion piece, and I know for a fact that none of our pieces ever said anything about migraines, sickle cell, et cetera.
So I can only assume that the sales rep probably verbally was doing this. All I can answer is for what promotion pieces we had.
So this has got to be -- you know, it's probably some aberrant sales reps, is the only thing I can assume. But I know the pieces that I pre-cleared with the FDA, and I approved, did not reflect any of these indications or

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non -- or patients who were not yet opioid tolerant.
So it probably, I'm deducing, it related to, you know, maybe sales activities, that way.
Q. What about some of the concerns raised by DDMAC?
I mean, you weren't aware of how they targeted physicians, were you?
MR. DIAMANTATOS: Objection to form. Foundation. Assumes facts.
THE WITNESS: I didn't know the details of how they chose which categories were targeted, if that answers your question.
BY MR. CRAWFORD:
Q. So, I mean, you're speculating that it was just some aberrant sales reps that caused this fine to be imposed and guilty plea, right?
MR. DIAMANTATOS: Objection. Form. Mischaracterizes the testimony.

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BY MR. CRAWFORD:
Q. Or do you know it was just aberrant sales?
MR. DIAMANTATOS: Let me finish my objection, counsel, please.
Objection. Form. Mischaracterizes the witness's testimony.
THE WITNESS: So I'm saying, all the written documents that they gave in a promotion that were supported by the company were all pre-cleared with FDA, submitted to the FDA, reviewed by the promotion review committee, and none of those pieces discussed these off-label uses, nor anything about patients who were opioid nontolerant.
So the pieces -- all I can address is, I trained the sales force. I told them what they had to do. I got the pieces cleared.

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What they did with that, you know, I didn't control that.
So I don't -- I don't know -- you know, it's kind of like going back to the details of what these reasons were. I don't know the specifics. All I can talk to are the pieces, the promotion pieces, that we had pre-cleared and sent to the FDA. And none of them, none of them talked about off-label use or nontolerant/opioid tolerant.
BY MR. CRAWFORD:
Q. But there are other aspects of sales and marketing. There's targeting of doctors. There's, you know, how they're trained.
And that wasn't your job to train the sales reps, was it?
A. Yes, I trained the sales reps on the RiskMAP program. Yes.
So I can't -- that's the only thing that I can tell you that I'm

responsible for. What happened outside of that, you know, what was -- what they were told to do outside of my area, I can't answer to.

Q. Right. Well, just -- we've marked Exhibit-28, which is the Government's Memorandum For Entry of Plea and Sentencing.

If you can just turn to Page 3, it does list the reasons here, or the off-label practices, and its training of its sales staff that the government believed ignored legal restrictions on promoting these drugs.

Do you see that on Page 3?

A. I do.

Q. Okay. And the first one is, Cephalon had its sales representatives call on doctors who would not normally prescribe the defendant's drugs in the course of the doctor's practice.

That doesn't have anything to do with the promotional pieces, does it?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

THE WITNESS: No. I think it goes back to the targeting issue, and that was not under my purview.

BY MR. CRAWFORD:

Q. And then they say, Cephalon trained its sales representatives on techniques to prompt the doctors into off-label conversations.

That was another claim by the government, right?

A. That's what it says here.

But all I did was train them on the RiskMAP and the concerns of the FDA. So that's the only thing I can really speak to.

Q. So do you think that sales reps received other training, maybe, that you didn't attend?

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: Yes. I was only -- I was only training for, like, an hour or an hour and-a-half. I don't know how long -- so they probably had a couple of days. So I don't know where that came from.

BY MR. CRAWFORD:

Q. It says, Cephalon's compensation and bonus structure encouraged off-label marketing.

That's not anything to do with regulatory or you, right?

A. Nothing.

Q. And then, et cetera, et cetera. I won't keep going into that.

A. Right.

Q. So -- all right.

MR. CRAWFORD: We'll mark the next exhibit.

MR. JENSEN: 29.

- - -

(Whereupon, Teva-Marchione

Exhibit-29, TEVA_CHI_00028341-691, was marked for identification.)

- - -

MR. CRAWFORD: We're going to mark four exhibits here just so we can kind of knock them out all at once.

- - -

(Whereupon, Teva-Marchione Exhibit-30, TEVA_MDL_A_08399245-251, was marked for identification.)

- - -

(Whereupon, Teva-Marchione Exhibit-31, TEVA_MDL_A_08399245-251, was marked for identification.)

- - -

(Whereupon, Teva-Marchione Exhibit-32, TEVA_MDL_A_02074924-969, was marked for identification.)

- - -

BY MR. CRAWFORD:

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Q. So at some point in -- if you take a look at what we marked here as Exhibits-29, 30, 31 and 32, 29 is a September 19th, 2006 letter from you to Dr. Rappaport, of the FDA, referencing the new drug application --

A. If I can correct you, it wasn't a letter from me. It was from Penny Levin.

Q. Very good. So she worked in your department, right?

A. Right. And that's what I was trying to remember. I was looking for my org chart, because I think that may have been the time I went to oncology. I can't remember. I mean, there was an overlap.

Q. Let's take a look at Exhibit-1. I want to get clear, because I think you were here in '07 to 2011, you went to oncology in '11.

So if you can check Exhibit-1 --

A. Yeah, maybe. I just want to

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double check.

Q. And make sure that you were here as senior director -- or as senior director and group leader, regulatory affairs --

A. Okay.

Q. -- from 2007 to 2011.

Is that right? Do you agree with that?

A. Yes. I think right around the time I got the approval for Fentora, we kind of switched. There was --

Q. Take a look at your --

A. I do understand the title.

But that doesn't necessarily mean that I wasn't not working on pain at the time. So it's a little -- I don't know exactly.

So all I'm saying is, when I was group leader, I may not have been -- they may have switched over yet. That's what I was trying to figure out.

I can still talk to this.

Q. When Fentora was approved,

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you were overseeing that effort, right?

A. It pretty much went over to Penny from that point on.

Q. Let's go, actually, to your first bullet point in the resume.

Actually -- yeah, your first bullet point under, Accomplishments.

A. Right.

Q. And you say, Successfully negotiated multiple product approvals.

And Fentora is on that list, right?

A. That's correct. This is a -- I mean, this is a supplement.

So I'm saying, after we got promoted, there was a transition.

Q. Right. But this is not a supplement.

This is an NDA for Fentora, right? It says, New drug application.

A. This supplement contains -- with regard to the Fentora RiskMAP.

Q. And this is one of your accomplishments, was to get this

Page 429

approved, right?

A. An amendment -- so it's an amendment to the NDA. Okay. I was just trying to ascertain.

So this was -- the amendment wasn't yet approved. So, yes, I was working on this at the time.

Q. So this is -- this is getting the approval of Fentora here in September of '06, you're working towards, right?

A. That is correct.

Q. And that was one of your accomplishments you outlined in your resume, right?

A. That's correct.

Q. So you were, in fact, as head of that regulatory department, overseeing this approval process, right?

A. Yes, I was.

Q. So -- and then we have here, they reference -- you state here in this letter, it's TEVA_CHI 00028341, Exhibit-29, you say, in your September

Page 430

19th letter -- or, actually, Ms. Levin does, 2006 letter, Reference is also made -- this is the last part of Paragraph 1.

Reference is also made to telephone conference request from Ms. Kim Compton, FDA project manager, on September 18th, 2006, who requested that a final submission of the revised Fentora RiskMAP, along with attachments, be submitted as an amendment to the NDA to reflect all changes agreed upon during the above-referenced FDA communications.

So this attachment here, this attaches the FDA -- or the RiskMAP, right?

A. It appears that way, yes.

Q. And the RiskMAP starts at Page, if I'm correct, 28345, right?

A. Yes.

Q. And it also references, in the September 19th letter, Reference -- this is the second sentence, Reference is also made to the discipline review

Page 431

letters, August 29th and September 7th.

So I have attached those discipline review letters as Exhibits-30 and 31.

Do you see those?

A. 30 and 31. Yes, I do.

Q. And those, in fact, are addressed to you, right?

A. They are.

Q. They're from the FDA.

And can you explain what these discipline review letters are?

A. I'd have to -- you know, I just got them.

But just in general, discipline review letter is FDA feedback for a -- you have to read it.

So it's the RiskMAPs associated with -- complete response -- oh, so this is associated with -- so a review -- a review letter is just comments back, it could be on any part of your NDA.

So this is obviously on our

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labeling. And the other part, RiskMAP. And the RiskMAP, at that time, was considered labeling.

Q. So they're making -- they're telling you what you needed to change in the Fentora RiskMAP, right --

MR. DIAMANTATOS: Objection.

BY MR. CRAWFORD:

Q. -- before it could be approved --

MR. DIAMANTATOS: Objection.

BY MR. CRAWFORD:

Q. -- in these letters?

MR. DIAMANTATOS: Objection to form. Vague.

And are you referring to all three exhibits? If you can just be clear so she can --

MR. CRAWFORD: 30 and 31. Very good. Thank you, counsel.

THE WITNESS: So 31 is here. So everything was considered draft, when you submit it under the NDA.

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So these are comments to change -- the comments to the RiskMAP that they want changed prior to they approved the FDA -- I mean, approve the NDA.

And, likewise, the changes to the package insert for Number 31.

BY MR. CRAWFORD:

Q. All right. And so in Exhibit-29, Ms. Levin is referencing these discipline review letters and indicating that the Fentora RiskMAP has changed, final submission to reflect the changes agreed upon, right?

A. Formal response -- so this constitutes Cephalon's response to the agency's requests. That's what it says here.

Q. So 32, then, was the approval letter for the Fentora NDA, right?

And that's addressed to you?

A. It was. Yep. Yes, it is.

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Q. So if you look at the fourth paragraph down, it says, This new drug application -- actually, before that.

Let's go through this. So the fourth paragraph down, it says, This new drug application provides for the use of Fentora for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

So that's the same indication as Actiq, correct?

A. That's correct.

Q. So only -- Fentora, like Actiq, could only be -- was only indicated for use in cancer patients, right?

MR. DIAMANTATOS: Objection to form.

Go ahead.

THE WITNESS: That's correct.

BY MR. CRAWFORD:

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Q. So the last paragraph, Your Fentora RiskMAP, it says, is an important part of the postmarketing risk management for fentanyl buccal tablet. The primary goals of your RiskMAP are to minimize the use of Fentora by opioid nontolerant individuals, minimize misuse of Fentora and minimize the unintended accidental exposure to Fentora.

So you understood the RiskMAP to be an important part of the postmarketing risk management, in the FDA's views, right?

MR. DIAMANTATOS: Objection to form. Speculation.

Go ahead.

THE WITNESS: Obviously, from the text it is an important part.

BY MR. CRAWFORD:

Q. Then it says, Your RiskMAP must include the following components. Implementation of a program and distribution of materials to educate

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prescribers, pharmacies, nurses and patients about the risks and benefits of Fentora.

Right?

A. That's what it says, yes.

Q. And then 3 -- skipping to 3 -- or 2, Implementation of a reporting and data collection system for safety surveillance.

And, 3, implementation of a plan to monitor, evaluate, and determine the incidence of use of Fentora by opioid nontolerant individuals, misuse of Fentora and unintended, accidental, exposure to Fentora.

So that was, according to the letter, what the FDA viewed as the primary goals of the RiskMAP, right?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: The components of the RiskMAP, yes.

BY MR. CRAWFORD:

Q. So it's saying here that the

Page 437

Fentora RiskMAP, submitted on August 31st, 2005, and finalized in your submission dated September 19th, 2006, and as described in the attached document, adequately addresses each of these requirements.

So they are referring to Exhibit-29 here, right, the RiskMAP attached to that? Is that your understanding of the letter?

MR. DIAMANTATOS: Objection to form. Calls for speculation.

BY MR. CRAWFORD:

Q. I'm trying to establish that that's the RiskMAP they approved, right?

A. I'm still -- submitted August 31 -- I'm just trying to find that.

Q. It says, Finalized in your submission dated September 19th, 2006 and as described in the attached document.

A. So it's 8/29, is that the date?

Q. It's September 19th, 2006.

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A. September 19th. I'm just trying to find that submission.
Q. That would be Exhibit-29.
A. 29?
Q. Yes.
A. Got you.
Q. And it's Page 28345.
A. Okay.
Q. What I'm trying to do is establish that the one you sent to them, or Ms. Levin sent to them on September 19th, 2006, is the one that they're referencing here in the approval letter that that's approved?
A. I understand. Thank you.
Q. Is that how you understood the letter?
A. Yes, that's how I understand it.
Q. So you understand the final RiskMAP that was approved is actually the one that is actually attached to Exhibit-29?
A. That's my -- yes.

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Q. All right. It states, This plan includes ongoing assessment and periodic reporting to FDA of the operation of the program and needed revisions, if any. Any change to the program must be discussed with FDA prior to its institution and is subject to the FDA's determination that the required components are still present. We expect your continued cooperation to resolve any problems regarding the Fentora RiskMAP that may be identified following approval of this application.
So it was your understanding that, in approving this, that there was an ongoing assessment and periodic reporting to the FDA on the operation of the RiskMAP program, similar to what you were reporting for Actiq, right?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: That's my understanding, yes.
BY MR. CRAWFORD:

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Q. And was somebody at regulatory in charge, again, of ensuring that reports were made to the FDA about the RiskMAP?
A. Yes. And in this case, it was Penny.
Q. Okay. So Penny took over that function from you for this, or did you take any responsibility for it?
A. I think anything only elevated to me if there was a significant issue or concern.
Q. But do you remember her elevating anything to you about the RiskMAP reporting for Fentora?
A. I don't actually remember.
Q. But she was, really, the primary responsible person for that?
A. Yes, she was.
Q. And then the approval letter does attach the label, at Page 928. You'll see a big black box there.
Is that a black box warning?
A. Yes, it is.

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Q. And can you explain to me what a black box warning is, in regulatory parlance?
A. So it shows concerns of the product that can affect safety and explains the FDA has revised, not just the concerns, but how you can address those concerns. So if you see a certain adverse event, how you can actually diminish it or treat that adverse event.
And that's what the box is.
Q. And they call it black box because it's in a black box, right?
A. That's correct.
Q. And it's the most serious type of warning you can give in a package insert or label, is a black box warning, right?
A. That's correct, yes.
Q. So it's -- a black box warning is always put right in the front on the first page, right?
A. Yes, that's correct.
Q. And here we have a black box

Page 442

warning for Fentora about it containing fentanyl, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid analgesics.

So there are black box warnings here, would you agree, that pertains to abuse of the drug, correct?

A. Yes.

Q. And the black box warning, the second paragraph, also contains a bolded warning about the indicated use for management of breakthrough pain in patients with cancer, right, who are already receiving -- who are tolerant to opioid therapy for their underlying persistent cancer pain; that's in the black box, too, right?

A. Yes, it is.

Q. Let's go to the next doc.

Actually, go to Page -- Exhibit-29. I had a couple of questions about the RiskMAP.

So this RiskMAP contains

Page 443

similar elements -- do you recall at all reviewing the RiskMAP for Fentora?

A. We did. It started out similar, based upon what we had for Actiq. It was right around the time the FDA actually was going to be issuing RiskMAP guidance. So they were trying to have consistency with other products.

And there were a lot of new elements that they took from the device group. A lot of it is, like, prospective -- so it's prospective analysis. And so it started to morph into a very different type of document than the Actiq one.

Q. All right. But it did contain a lot of elements similar to the Actiq one, right?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: I think the most significant difference was, because of the FDA's -- one of the most critical concerns about Actiq

Page 444

was its appearance of a lollipop, which would be enticing to children, whereas Fentora was a buccal tablet, so it didn't have -- you know, it looked like a pill or lozenge. So they weren't as concerned of the pediatric -- I shouldn't say weren't as concerned, but it wasn't the emphasis as much as it was for Actiq.

BY MR. CRAWFORD:

Q. But certainly misuse and abuse were a concern?

A. Yes, they were.

Q. So, in fact, if you look at Page 28347, which is about the sixth page in here, that's the first page under, Background.

A. Yes.

Q. Do you see that, under the middle there, it says, As Fentora contains a potent opiate, fentanyl, the SECURE program is focused on minimizing

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the three risks associated with, one, use of Fentora by opioid nontolerant individuals, misuse, abuse and diversion of Fentora and unintended exposure to Fentora.

That's similar concerns or rationales that were behind the Actiq RiskMAP, right?

A. Well, the pediatric issue was removed.

Q. Good point, yes.

So if you go to the next page, it's Page 4 of the RiskMAP, up at the top, it says 4.

But if you go to the bottom, it says, In designing this RiskMAP, Cephalon has focused on ensuring the integrity of its supply chain for Fentora; 2, tools that can be used to educate broadly; and, 3, mechanisms by which cases of diversion or abuse can be detected promptly. In this regard, Cephalon will monitor geographical evidence of abuse through the use of the

Page 446

RADARS system, see below, to assure that rapid interventions can be applied to areas where there may be a signal of increasing abuse potential.

So the hope was here that the RiskMAP would allow Cephalon to identify -- that they would educate, using these tools, educate broadly, but also to identify problems and focus in on solving them, right?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

BY MR. CRAWFORD:

Q. Is that a good summary of what the FDA wanted?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

THE WITNESS: One of the biggest issues in reference to the SECURE program was to try to have a closed-loop system where, if something was going to be diverted

Page 447

from any point from the manufacturer to the patient, that there was a more controlled tracking of that.

BY MR. CRAWFORD:

Q. And if you turn to Page 9, it lists the RiskMAP goals and objectives.

And under 2.1, one of the goals was abuse, misuse and diversion of Fentora should not occur; is that right?

A. That's correct.

Q. And then Goal 2 is elaborated upon in 2.2.2. In Roman Numeral III, it says, Reduce the potential abuse, misuse and diversion of Fentora by, A, providing education to healthcare personnel and to pertinent nationwide demographic communities; B, performing ongoing surveillance of and reaction to geographical outbreaks of abuse, misuse and diversion; and, C, cooperating with and providing assistance to law enforcement in investigations of

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incidents of abuse or diversion.

You understand this was one of the responsibilities of the company here in preventing abuse and misuse that the RiskMAP imposed, right?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: That's my understanding.

BY MR. CRAWFORD:

Q. And then on Page 11, there is, 3, The overall strategy for prescribing, dispensing, using Fentora. And 3.1 is, Physician education.

So they're saying here, basically -- I don't want -- I am not going to read it all, but they're basically outlining steps that the company was to take with regard to education of physicians about the drug, right?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: Right.

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BY MR. CRAWFORD:

Q. And then going to Page 15, down at the bottom, 3.6.1, Strategy and tools associated with Goal 1, Fentora should be used only by opioid-tolerant patients with cancer.

It does state, A variety of tools will be used to communicate and reinforce the message that Fentora should only -- should be used only by opioid-tolerant patients with cancer.

So that was -- the RiskMAP contains, then, a list of tools that were available to Cephalon to make sure that only cancer patients use the drug, right?

A. That's my understanding.

Q. Okay. And then at Page 16, the first full paragraph there, it says, From the outset, healthcare professionals will be alerted to the risks of this new product through product labeling and promotion. They will be educated about the product's approved indication, as well as about the definition of opioid

Page 450

tolerant as described in the package insert.

Tools directed -- moving down, Tools directed towards prescribers will include introductory letters, visits and assessments by Cephalon field representatives, Fentora website and targeted education and outreach programs directed to pain centers of excellence and professional societies.

So these were tools that the FDA expected Cephalon to use proactively to educate doctors about the proper use of the drug, right?

MR. DIAMANTATOS: Objection to form. Foundation. Speculation.

Go ahead and answer.

THE WITNESS: Just to be clear, we proposed this to the FDA. So we voluntarily are saying, we're going to be doing this, and the FDA agreed.

So it wasn't that the FDA

Page 451

said, you do this and we agreed.

We prompted this.

BY MR. CRAWFORD:

Q. Very good point.

So you -- the company was involved in drafting this up, and the FDA provided comment back?

A. Exactly.

Q. And so this was the final one approved.

But, you're right, the company was the one that said, this is what we'll do to make sure the drug is safely and properly used?

A. That's correct, yes.

Q. Thank you.

So if you could go to Page 26, you have a table there. It's a Goal 2 summary table, Goal 2 being misuse, abuse and diversion of Fentora.

These charts here outline the various tools that Cephalon intended to use to ensure that there was no misuse, abuse, or diversion of Fentora,

Page 452

right?

A. And that's correct. It's written in terms of the loop, you know, so the points of intervention. So every place that anything touched hands, how they would communicate the proper information.

Q. And so on Page 28, some of these tools, looking down, the third one down, Take a look at that, starting with, Launch professional societies.

A. Right.

Q. So professional societies, at launch, will be contacted to offer educational opportunities to learn about Fentora and key messages and risks described in the RiskMAP, including the risk of misuse, abuse and diversion.

That was one tool that was being offered, right?

A. More than offered. It's more --

Q. Implemented?

A. Implemented, yes.

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Q. And then going to 29, you have several ongoing tools.

One -- the top one being, Cephalon will implement medical education directed to geographic hotspots to focus on preventing and/or minimizing misuse, abuse and diversion of prescription drugs.

Below that, Launch an ongoing -- two below, Cephalon will support independent education on prescription drug misuse, abuse and diversion targeted to physicians likely to prescribe Fentora.

So I didn't read them all, but these were tools that the -- that Cephalon had agreed to utilize to prevent misuse and abuse, and the FDA agreed with this plan and approved Fentora, conditioned upon Cephalon executing this plan, correct?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: That's my --

Page 454

yes, that's my understanding.
BY MR. CRAWFORD:
Q. Go to Page 54. I just want to point out one more tool here.
The second one down, Number 6, Page 54, at the top. Second one down, Number 6.
So that one is a -- the tool is, Direct risk communication by Cephalon field representatives.
So one of them was, At launch and ongoing, prescribers will be informed, in person, of the key messages and elements of the Fentora RiskMAP, including the potentially life-threatening risk of use by an opioid nontolerant individual, the high potential for Fentora abuse, as well as the risk of misuse and diversion and the potentially life-threatening risk of accidental use of Fentora in children or adults.
That was, again, a tool that Cephalon intended to use with its sales

Page 455

force, right?
A. Yes.
Q. Okay. Moving down to 10, on the next page, again, Physician education directed at pain centers of excellence.
What is a pain center of excellence? Do you know what that is?
A. No, I don't. Sorry.
Q. Were these tools that the marketing department were supposed to make sure were implemented?
MR. DIAMANTATOS: Objection.
BY MR. CRAWFORD:
Q. Marketing and sales, rather?
MR. DIAMANTATOS: Objection to form. Foundation.
THE WITNESS: So they were -- so, I'm sorry, can you repeat that question?
BY MR. CRAWFORD:
Q. Yeah.
I'm just wondering, these were tools -- if they deal with the sales force and physician education through the

Page 456

sales force, that would be a tool that the marketing and sales department were required to ensure were utilized, right?
A. I'd have to check. It could be -- it could be medical affairs, too, the MSLs. So it could have been -- it could have been that group also.
Q. Right. But it could also be sales and marketing, if they're sending out sales reps, right?
A. That's true. But does it say sales reps? I didn't know if it said that specifically.
Q. Yes, it did -- the last one we read was direct risk communication by Cephalon field representatives, which is a sales representative, right?
A. I'm not quite sure. It could have been MSLs. I don't know how they define that, at that point.
Q. Okay. Well, 10 is, Launch an ongoing -- Cephalon will contact each of the identified top 25 pain centers of excellence to offer further educational

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opportunities to learn about Fentora, including the three principle risks identified in the RiskMAP. Specific risks of use by opioid nontolerant individuals, the risk of misuse, abuse, and diversion, and the risk of accidental exposure to Fentora will be addressed.
So the pain centers are supposed to be contacted, under this plan, to educate -- to offer educational opportunities to learn about Fentora, correct?
A. It appears that way, yes.
MR. CRAWFORD: So moving on to Document 661.
- - -
(Whereupon, Teva-Marchione Exhibit-33, TEVA_MDL_A_00038282-295, was marked for identification.)
- - -
MR. JENSEN: Exhibit-33.
BY MR. JENSEN:
Q. We've marked Exhibit-33,

Page 458

which is a -- let me ask you this, do you recall, at any point in time, trying to seek an expanded indication for Fentora for noncancer uses?

A. Vaguely.

Q. And were you involved in that effort?

A. Well, I was at this meeting, so I probably was.

Q. Okay. All right. So this is a letter from the FDA to you at Cephalon, dated July 17th, 2007.

So what do you recall about -- and it includes minutes from a meeting here. The meeting minutes, the meeting objective -- like you pointed out, you attended this meeting, correct?

A. Yes.

Q. Right. And who is Eric Floyd?

A. That was my manager at the time.

Q. All right. And Penny Levin as well, she worked in your department?

Page 459

A. Right. She reported to me.

Q. All right. And, again, Mr. Rappaport at the FDA attended the meeting, correct?

A. Yep.

Q. And the meeting objective is stated below. And it is -- it states that the purpose of the meeting was to provide the sponsor with feedback on the questions in their May 11, 2007 meeting package, which were specifically related to the submission of a supplemental new drug application to expand the indication for their product.

So what was -- what was Cephalon trying to do here?

A. I'm deducing they were trying to have the product approved for a broader indication than for just cancer.

Q. And what was the broader indication they were seeking?

A. For any -- for anybody who has breakthrough pain and who is tolerant to opioid therapy, for their underlying

Page 460

persistent pain.

Q. And do you recall what the FDA's response was in this meeting?

A. No, I'd have to review it. Sorry.

Q. Maybe -- okay.

They had a bunch of responses here before they could approve it.

They were trying to give you -- were they trying to give you some kind of guidance on getting it approved?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: That's -- that's what the meeting -- the intention of the meeting, yes.

BY MR. CRAWFORD:

Q. I think I want to direct your attention in particular to Page 6 of the letter, at the bottom, Question 11.

These are questions posed by the company to the FDA prior to the meeting, right?

Page 461

A. That's correct.

Q. And this question was, Does the agency concur that the currently approved RiskMAP for Fentora is acceptable to support the use of Fentora in opioid-tolerant patients with persistent pain?

That means with -- broadly, anyone with persistent pain, whether Fentora should be approved, right?

A. That's my understanding.

Q. And so the FDA response is here. And the FDA -- what, generally, was their response to this question?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: Do you want me to read it to you?

BY MR. CRAWFORD:

Q. Well, you were at this meeting. And you can either read it -- you're welcome to read it or give your recollection of what they thought about the RiskMAP.

A. I just have to review it, because I just don't remember, sorry.
Q. Sure.
A. So they -- they're saying that the RiskMAP that's currently approved for the cancer subset would have to be broadened and -- because it may increase the risk of inadvertent exposure, as well as misuse.
And so they want to have the RiskMAP be evaluated to consider the increased risks.
Q. And did they have anything to say at the meeting and in their response about the current success of the -- the success of the current RiskMAP in place for Fentora?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: I can read what is stated here. I don't have a recollection.
It says, It is clear that this program has not been entirely

successful, based on the known postmarketing use patterns.
BY MR. CRAWFORD:
Q. All right. Let's read the whole thing here.
It says -- at least the first paragraph. The currently approved RiskMAP was intended to minimize the risk of overdose and death as a result of use by improperly selected nonopioid-tolerant patients, inappropriate use by noncancer patients and inadvertent exposure of household contacts. It is clear that this program has not been entirely successful, based on the known postmarketing use patterns.
So in your view, and in this meeting, was the FDA expressing to you that it didn't think the current RiskMAP was working with regard to stopping inappropriate use by noncancer patients as one element?
MR. DIAMANTATOS: Objection. Form. Calls for speculation.

THE WITNESS: It says "not entirely successful," is how I see it.
BY MR. CRAWFORD:
Q. But that was one of their responses here.
So going down to the bottom of that section, under discussion, with respect to off-label use, it says, Dr. Hertz stated that the sponsor had the first RiskMAP of this kind with their Actiq product, noting that the plan was not very successful in limiting off-label use.
So he's referring to the whole Actiq RiskMAP and how it really was not successful, right?
MR. DIAMANTATOS: Objection to form. Calls for speculation. Foundation.
THE WITNESS: That's how she references this.
BY MR. CRAWFORD:
Q. And so it says that, The

division cannot recommend how to better formulate the plan. The sponsor must propose new ways to address and manage the risks of the product in the proposed expanded population.
So it was putting the burden, the FDA, on Cephalon to come up with a viable plan that the FDA thought could work to minimize the risk of abuse, if it expanded the indication, right?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.
THE WITNESS: That's how it is stated here.
BY MR. CRAWFORD:
Q. So if you go to the next page, the FDA is expressing some -- why it's expressing reservations over expanding the use, based on this -- concerns about the RiskMAP here.
It does say, I'll just read here at the bottom, The sponsor stated that they have surveillance and education

Page 466

in the current plan, but the plan to boost the educational portion of the plan in regard to proper patient selection -- I don't know if I'm reading that right.

Oh, okay. Strike that.

It states here, The FDA stated that they have surveillance and education in the current plan, but plan to boost the educational portion of the plan in regard to proper patient selection. Dr. Hertz stated that they -- or the agency agreed with this, but noted that Actiq failed in this goal.

So the FDA is concerned about expanding based on the bad experience with Actiq, correct?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation. Mischaracterizes the exhibit.

THE WITNESS: So it's kind of strangely written. It says the sponsor was going to boost it for a noncancer indication. And Dr.

Page 467

Hertz stated that the agency agreed with this, but noted that Actiq failed in its goal.

Well, Actiq never -- we never tried to get an expanded indication. So it's kind of not really written that correctly.

BY MR. CRAWFORD:

Q. Fair point. Yep. All right.

MR. CRAWFORD: We'll mark the next exhibit.

MR. JENSEN: 34.

- - -

(Whereupon, Teva-Marchione Exhibit-34, TEV_FE00116840-843, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. And this is the Exhibit-34, TEV_FE00116840. This is -- this is addressed to Ms. Levin, who is in your department.

This is the FDA finding that

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the -- the date is September 17th, 2008. Actually, it was sent September 12th on the back.

This was the FDA finding that the request for a new expanded indication to be not approvable, correct?

A. That's correct.

Q. Okay. So do you know if the FDA ever approved an expanded indication for Fentora for noncancer patients?

A. I believe they never did.

MR. CRAWFORD: Next I'm going to mark Document 303. It's going to be Exhibit-35.

- - -

(Whereupon, Teva-Marchione Exhibit-35, TEVA_MDL_A_00349300-301, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. I think we're getting very close to the end here.

So at some point, do you

Page 469

have a recollection -- I think we talked about a REMS at the beginning of the deposition, right, a risk evaluation mitigation strategy?

A. Yes.

Q. Right. And at some point, the FDA had indicated it wanted to impose a REMS program on Actiq and Fentora, correct?

MR. DIAMANTATOS: Objection. Form.

THE WITNESS: A REMS? So it's a timing issue. I don't know if they ever wanted to get a REMS on Actiq, because we stopped marketing by the time the REMS came into place.

But yes for Fentora.

BY MR. CRAWFORD:

Q. All right. And were you or the company involved in spearheading any effort to -- for the industry to put together a proposed REMS for the FDA?

A. So that was at the time when

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I -- my new manager, Jim Ottinger, came. So I -- I was asked to kind of help him get up to speed, because he was the person spearheading that. So I worked a couple months overlapping with him on that.

Q. What was his name again?

A. Jim Ottinger, James Ottinger. He was the vice president of regulatory.

Q. How do you spell his last name?

A. O-T-T-I-N-G-E-R.

Q. And he was leading an effort to -- collaboration with the other drug makers that made that class of drugs, the TIRF REMS, right, or the TIRF products to prepare a REMS, right?

A. Let me -- I'm sorry, let me just back up.

It was a transition between Eric Floyd, who left, and then Jim Ottinger came. So I think at that point, Eric Floyd was leading that, left, they

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asked me to kind of cover for him until Jim Ottinger, my new manager, got up to speed to take that over.

Q. And was this Teva, at this time, it was -- well, it wasn't Teva.

It may have still been Cephalon, right?

A. Yeah, I think it -- I think it was Teva. It was around that transition time, yes.

Q. So Teva or Cephalon were leading the effort, amongst this class of drugs and manufacturers, to prepare and propose a REMS for the FDA?

A. You know, I'm trying to remember --

MR. MUDGE: Object to form.

BY MR. CRAWFORD:

Q. Let me back up and strike that.

So there was some kind of group formed of manufacturers, right, to do something with regard to the REMS, right?

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MR. DIAMANTATOS: Objection to form. Foundation.

THE WITNESS: When this started, I was not -- when -- an expansion came more, I believe, from the FDA than from us.

So my recollection, and please, you know, it was a time when I was transitioning off of the program, I was under the impression that the FDA was the one that was trying to put a class together, because -- so every single manufacturer wouldn't have, you know, to go through having physicians attest to something.

So I could be wrong. But I thought it was the FDA who was trying to group it, or maybe discussions with different manufacturers, because -- for consistency.

BY MR. CRAWFORD:

Q. So the manufacturers were

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all operating independently in interfacing with the FDA, or was there kind of a unified group working together on the manufacturers' side?

MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation.

THE WITNESS: So, obviously, initially, it was -- manufacturers were working individually. And I don't know who led -- or who had the understanding to make it into a group.

In my recollection, I thought it was initiated by the FDA. But because I was not as involved at that point, I'm probably not the best person to answer that. But that was my understanding.

So all the stopgaps that we were putting in to the chain of events, it would be consistent amongst all the manufacturers

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doing the same thing. And I think -- so I think that was the issue, and it wouldn't be repetitive as much for a doctor to have to do multiple -- everything in the short-acting class or whatever. That was my recollection.
BY MR. CRAWFORD:
Q. Yeah. I'm just trying to find out if there was a group of manufacturers that were working together to make some proposals to the FDA?
A. So I remember --
MR. DIAMANTATOS: Objection to form. Foundation. Asked and answered. Speculation. Vague.
THE WITNESS: I remember, actually, Sharon Hertz asking us to go and talk to other manufacturers. And it was -- it was kind of soft, because they didn't legally have the ability to make you work together.

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But I remember saying, well, how can we do that? And the more I think about it, the more it was directed by the FDA.
BY MR. CRAWFORD:
Q. All right. But there was a group that got together and worked on it, of manufacturers?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered repeatedly. Calls for speculation.
BY MR. CRAWFORD:
Q. If you know.
A. I think -- I know we started talking to one of them, you know, because they -- they kind of prompted -- they kept prompting us to do that.
And, again, that's about the time I went off the project.
Q. And you say talked to "one of them," one of the other manufacturers?
A. Yeah. And I can't remember which one.

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Q. Okay. That's fine.
So we marked here as Exhibit-35 a timeline here, TEVA_MDL_A_00349300.
This is just a timeline we found in the Teva documents called, Timeline of Events Leading Up to the REMS Requirement For Opioid Analgesics.
And I thought maybe this is a good shortcut to trigger your memory of the steps and processes that were undertaken here.
So the first point that I wanted you to look at, just for reference, September 25th, 2006, says, Fentora fentanyl buccal tablet approved for use in breakthrough pain in opioid-tolerant patients with cancer.
So that at least provides us a guide point. That's an accurate date, correct?
A. I believe so.
Q. And then -- and then June 22nd, 2007, it says, Fentora pre-SNDA

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call with the FDA to discuss SNDA risk minimization action plan, RiskMAP, when FDA indicated concerns whether or not the approved RiskMAP was as effective as possible. Concerns arose because of new information regarding the safety of Fentora, including reports of a death of a patient who was not opioid tolerant and taking Fentora for a migraine, conversion from Actiq to Fentora, substitution at pharmacy and patients not understanding dosing.
So do you recall, during this June 2007 time period, the FDA raising these concerns?
MR. DIAMANTATOS: Objection to form. Foundation.
THE WITNESS: I was obviously on the project at the time. I just don't remember that specific incident.
BY MR. CRAWFORD:
Q. All right. And then in August, they're talking about, Cephalon

notified of additional reports of deaths due to the same reasons as June 22nd discussion with FDA.

Do you recall that notification?

MR. DIAMANTATOS: Objection to form. Foundation.

THE WITNESS: You know, I don't remember.

BY MR. CRAWFORD:

Q. All right. Skipping ahead, the next page, to March 27th, 2008.

It states, FDA issues federal register that identifies Actiq as one of the 16 drugs needing a REMS by September 21st.

Do you see that?

A. I do see that.

Q. Does that refresh your recollection that maybe the FDA wanted a REMS for Actiq?

MR. DIAMANTATOS: Objection to form. Foundation.

THE WITNESS: I believe I

was off the project by then. And to be honest, I didn't even remember if Actiq was still on the market -- you know, I thought they -- I didn't know -- they weren't promoting it, maybe. It was on the market. But I just don't remember that.

BY MR. CRAWFORD:

Q. All right. And then September 17th, 2008, Cephalon submits initial REMS proposal for Actiq to the FDA.

Were you involved at all in that submission to the FDA?

A. Not that I can recall.

Q. All right. February 6, 2009, FDA informs 15 drug manufacturers that will require a REMS for certain opioid drug products to ensure safe use.

Do you recall that at all?

A. No, I don't.

Q. March 3rd, 2009, Cephalon withdraws the amended RMP for Actiq since

it was never approved, and a REMS will be now substituted instead.

Do you recall withdrawing the amended RiskMAP for Actiq in '09?

MR. DIAMANTATOS: Objection. Form. Foundation.

THE WITNESS: No, I don't.

BY MR. CRAWFORD:

Q. And April 2nd, 2009, states, Cephalon submits proposed REMS for Actiq and proposed REMS for Fentora to the FDA.

Were you involved at all in preparation of a submission of a proposed REMS for Actiq and Fentora around this April 2009 time period?

A. Not that I can recall.

MR. CRAWFORD: Let's mark the next exhibit. That would be 632.

- - -

(Whereupon, Teva-Marchione Exhibit-36, TEVA_MDL_A_00651161-168, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. So we marked now a June 11th, 2010 letter from you to Dr. Rappaport stating -- it's document TEVA_MDL_A_00651161.

It states, At the request of the agency, Cephalon representatives met with FDA on May 25th, 2010, with the intention of resolving outstanding issues related to the REMS for both Actiq and Fentora so that these strategies can be implemented as soon as possible. The submission contains Cephalon's minutes of the discussions during the May 25th meeting.

And it's signed by you.

So was this -- do you recall now being involved in these discussions around June 2010 time period?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: I do recall now. This is when I was pulled

back -- let me see. Who was there?
This is when Jim Ottinger first came. This was that period. Yes, I do recall this.
BY MR. CRAWFORD:
Q. So you were involved in discussions with the FDA about the Actiq and Fentora REMS and getting that in place?
A. I was on the transition team during this, yes.
Q. And if you look at the last page, it looks like you had attended the meeting as senior director and group leader, regulatory affairs, Cephalon, correct?
A. That's correct.
Q. And you attended with Jim Ottinger, right? That was when you were helping him transition on this, right?
A. That's correct, yes.
Q. So that fits within your recollection. But at least it gives us a

time period.
You were involved here in this 2010 time period, right?
A. Right.
MR. CRAWFORD: So now we're going to mark as Exhibit-587 -- I'm sorry, Document 587, that will be Exhibit-37. And then we're going to attach to that two documents which were attachments, the Actiq REMS and the Fentora REMS.
I don't have a copy of the Actiq REMS. I just have the electronic copy. But I want to kind of get these into the record, since it's regulatory and she's our regulatory person.
So I'm going to flash it on the screen and see if counsel is agreeable to my --
MR. DIAMANTATOS: If you're going to show her an exhibit and intend on asking her questions

about it, I need you to show her the entirety of the exhibit so she can review it and comment on it. Flashing it on the screen is not good enough.
MR. CRAWFORD: How about if I get her to acknowledge and not ask her questions about the document?
MR. DIAMANTATOS: No. If you're going to ask her any questions about a document, she has to be given the opportunity to review it.
I'm not trying to be difficult. If you want to take the time to go through it on the screen page by page and give the witness the ample opportunity to review it appropriately so she can intelligently answer your questions, I don't necessarily have an objection to that, since you don't have a paper copy.

MR. CRAWFORD: Let's do that, then.
- - -
(Whereupon, Teva-Marchione Exhibit-37, TEVA_MDL_A_07679381-383, was marked for identification.)
- - -
(Whereupon, Teva-Marchione Exhibit-38, TEVA_MDLA_A07679384-521, was marked for identification.)
- - -
MR. CRAWFORD: So 587 is Exhibit-38. And then the Actiq REMS, we'll get a hardcopy, will be 39. And then the Fentora REMS is 40, because that's how the document numbers go sequentially.
BY MR. CRAWFORD:
Q. After that meeting with the FDA and Mr. Ottinger was involved, did you kind of drop off the REMS project?
A. Yes, that's correct.

Q. So you weren't around for the actual finalization of the REMS plan, right?
A. Not that I can recall. I don't think I was.
Q. And did Mr. Ottinger, by that point, take over kind of the duties for the company with regard to the final negotiations with the FDA on the REMS?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: I don't remember. I'm seeing Susan Frank's name here, so she may have done that.
BY MR. CRAWFORD:
Q. And so we marked here 37. This is an e-mail.
I don't see you on this e-mail, 37, but it's attaching the two REMS documents that we marked as Exhibit-38 and 39, or we will mark for 38 for Actiq.
Take a look at 39. I just

want to see, from your regulatory experience, does that look like an FDA approval of a REMS, at least for Fentora, Exhibit-39?
A. Yes, it does.
Q. Okay. All right. I'm having a little confusion here about what we've attached, and I apologize.
So this e-mail chain, what exhibit is that? Do you have marked there on your right hand?
A. The e-mail chain is 037.
Q. So that's 37. And then we marked --
MR. DIAMANTATOS: Just to be clear, do you want to say the Bates for the record?
MR. CRAWFORD: Yes, that's good. Thank you. I think that will make it clear.
TEVA_MDL_A_07679381.
And then what follows sequentially is Exhibit 38, which I believe is an attachment,

TEVA_MDL_A_07679384.
BY MR. CRAWFORD:
Q. That document states that, This supplemental new drug application proposes modifications to the approved Fentora -- REMS for Fentora. We have completed our review of this supplemental application as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.
So 38 is, you would agree, from your regulatory experience, I know you're not on the e-mail, but that would be an FDA approval of the REMS, right, for Fentora.
A. That's my understanding.
MR. DIAMANTATOS: Objection to form.
BY MR. CRAWFORD:
Q. And then 40, is that the missing one?
MR. JENSEN: 39 is the missing one.

MR. CRAWFORD: 39, sorry.
Can we bring up 39 on the screen?
BY MR. CRAWFORD:
Q. I think it's just a similar one.
And I want to ask you the same question, if that looks to you like an approval. And you're welcome to flip through as many pages as you want until you feel comfortable that it would be an approval of the Actiq REMS.
And he's going to bring it up on the screen.
And that's all I'm going to ask you about that, because you weren't present at the time?
A. No, I wasn't.
MR. CRAWFORD: Why don't we come back to that?
I want to mark the next exhibit, which is Document 635.
MR. JENSEN: Exhibit-40.
- - -

(Whereupon, Teva-Marchione Exhibit-40, TEVA_MDL_A_08261145.xls, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. Now, when you were heading up that regulatory department, did you keep -- was there a call log or a contact log with the FDA that was kept in the department?

A. There was. There was some informal calls, I think -- yes. When there were formal telecons and meetings, there was a document that we would fill out.

I believe, though, informal calls we also logged, to the best of my recollection.

MR. CRAWFORD: And can we have a copy of the exhibit for the witness, please?

MR. JENSEN: She has it.

BY MR. CRAWFORD:

Q. We marked Exhibit-40, which is TEVA_MDL_A_08261145.xls.

So this appears to be, what it states is, Actiq official correspondence log. Starting with 11/11/96, and it goes through 3/8/2005.

Does this look familiar to you as a type of correspondence log that was kept for your department?

A. I mean, probably. So many of these logs that you deal with. So it looks reasonable.

Q. So it was the practice of your department, during the entire time you were there, to keep some kind of log of contacts and communications with the FDA?

A. Yes, that's correct.

Q. And here there are -- you do keep a log of submissions of promotional materials to DDMAC, right?

A. That's correct.

Q. So if there was any back-and-forth with DDMAC, and

correspondence, at least, that should be reflected in the logs that were kept with the department, right?

MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.

THE WITNESS: That's the process.

BY MR. CRAWFORD:

Q. So you had voiced some concern that DDMAC kept changing its demands on what it wanted on promotional materials.

If that was in correspondence, that should be reflected in this official correspondence log, right?

A. So that was the details that were in the letter. When we -- I expressed those concerns at that meeting. Before then, we never -- I don't know if I actually wrote to them and expressed the concern.

So it's -- the details are

within -- when you see the conflicting information, you have to look at each of the MACMIS numbers that are there, you see MACMIS ID.

So every time we submitted the document, we got an MACMIS number.

Q. What is an MACMIS?

A. It's a numbering system from the FDA, from DDMAC.

Q. You're pointing to something on Exhibit-40.

What are you pointing to?

A. Oh, like --

Q. Here it is. The submission number?

A. Right.

Q. So, anyway, if it was in writing, an exchange between DDMAC and you, it should show up in this log, right?

A. It should, yes.

Q. So when you're talking about stuff that may have been transmitted in writing that you were concerned about

later and addressed with them verbally, that dealt with these past MACMIS exchanges, right?

A. Correct.

You would have -- you would have to go into a specific one and show -- they would tell you to do one thing and they would have to find another one to say that they reversed their issues.

Q. All right.

MR. CRAWFORD: I got one more exhibit to attach. That would be 570.

MR. JENSEN: Exhibit-41.

- - -

(Whereupon, Teva-Marchione Exhibit-41, TEVA_MDL_A_08475177-178, was marked for identification.)

- - -

BY MR. CRAWFORD:

Q. Did you ever do any kind of analysis, while you were at Teva or

Cephalon, about reprints and how they should be used to comply with regulations, reprints of journal articles?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: Excuse me, I don't understand specifically what to do with reprints --

BY MR. CRAWFORD:

Q. Yes. Advising the company on what the regulations were with disseminating reprints, under FDA regulations.

MR. DIAMANTATOS: Objection to form. Foundation.

BY MR. CRAWFORD:

Q. We've marked here Exhibit-41.

It's an e-mail from you to Eric Floyd, Forward: Good reprint practices, review team.

You state, Eric, if you have a break from your meeting, could you

please call to discuss? I have a review meeting today on this, and I wanted to talk to you before that meeting, if possible. Thanks, Carol.

So do you recall anything about dealing with reprints around this 2009 time period and having review meetings?

A. Let me see.

So I remember that the compliance group that was supporting the CIA wanted to have a policy about reprint dissemination, and I went to a meeting where they were proposing a policy.

Q. And it was about this 2009 time period?

A. I believe so.

Q. And did you -- do you recall anything about that meeting, any details?

MR. DIAMANTATOS: Objection to form.

THE WITNESS: So when they proposed a policy, I don't know if I necessarily agreed with the

policy. And I was asked just to kind of improve it, and it was -- I think -- I think the understanding was that the compliance group had a deadline to meet and, you know, they didn't want a lot of back-and-forth on the policy, which I didn't necessarily agree with all the components.

And so I -- I wanted to alert my manager that, you know, this may be an issue, so I just wanted to talk to him.

BY MR. CRAWFORD:

Q. Just the final thing, let's throw up 39, which I just wanted to see if you agree that that looks to you like the FDA approving the Actiq REMS in the supplemental approval, similar to the Fentora one that was attached.

And, again, we'll get a hardcopy, an electronic copy, to the court reporter on that, and counsel.

MR. CRAWFORD: Forward a copy to counsel here, and the court reporter.
MR. DIAMANTATOS: Do you mind calling out the Bates?
MR. CRAWFORD: The Bates number, TEVA_MDL_A_074679522.
BY MR. CRAWFORD:
Q. What we have here is a --
MR. CRAWFORD: Can we go down to the date? Scroll down.
THE WITNESS: The date is actually the last page.
MR. DIAMANTATOS: I'll note for the record this is a 142-page document.
BY MR. CRAWFORD:
Q. Right. 12/28/11.
It's similar to the other Fentora one that was attached, I'll represent.
If you want to scroll through it, but all I want to ask is, does this look like the approval for the

REMS for Actiq?
A. Yes, it does.
MR. CRAWFORD: That's all I have. And I pass the witness. Thank you.
THE WITNESS: Thank you.
VIDEO TECHNICIAN: Going off the record at 5:56 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 6:01 p.m.
- - -
EXAMINATION
- - -
BY MR. GASTEL:
Q. Good evening, Ms. Marchione.
My name is Ben Gastel, and I represent a group of plaintiffs in the state of Tennessee that have been cross-noticed into this deposition today.
MR. GASTEL: We normally

begin these examinations with an objection. So I'll lodge my standard objection with the record that we object to the deposition going forward on behalf of my Tennessee clients, for Teva's failures to meet its obligations under the state, federal cooperation protocol, as we've laid out in our previous depositions and in our motion to quash.
BY MR. GASTEL:
Q. Subject to that objection, I am going to have some questions for you. I'll be a lot shorter than Mr. Crawford's examination throughout the day.
As I stated, the people that I represent are in the state of Tennessee.
So I'll begin with a question that, for your work for Cephalon and later Teva, did you ever have an opportunity to travel to the state of

Tennessee?
A. I don't think so, no.
Q. Did you ever review any records of the Tennessee Department of Health related to Tennessee's opioid crisis?
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: No, I haven't.
BY MR. GASTEL:
Q. Do you have any understanding, as you sit here today, about prescription -- about rates of prescriptions for prescription opioids in the state of Tennessee?
A. No, I do not.
Q. We've looked at a lot of documents today showing concerns by Cephalon, Teva and the FDA about abuse and misuse of opioids.
Throughout your role as director of regulatory affairs with Teva and Cephalon, you knew that there were

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problems with abuse and misuse of opioids throughout the country, right?
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: Generally, yes.
BY MR. GASTEL:
Q. And that would include abuse and misuse of prescription opioids in states like Tennessee, right?
MR. DIAMANTATOS: Objection to form.
Go ahead.
THE WITNESS: Not specifically. But in general, country-wide.
BY MR. GASTEL:
Q. You went through the Fentora RiskMAP with Mr. Crawford earlier today, and he read you a portion of that that referenced geographic hotspots.
Do you remember that document and that testimony?

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A. I remember that phrasing, yes.
Q. Do you know if Cephalon or Teva considered Tennessee a geographic hotspot for abuse?
A. Nothing was ever mentioned specifically about any particular hotspots to me.
Q. Do you know what metric is used to determine a geographic hotspot for prescription opioid abuse?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: No, I do not.
BY MR. GASTEL:
Q. I'm going to hand you a document that we're going to mark as Exhibit-42.
- - -
(Whereupon, Teva-Marchione Exhibit-42, TEVA_MDL_A_08380029-030, was marked for identification.)
- - -

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MR. GASTEL: I've got a copy for you, counsel.
THE WITNESS: Thank you.
BY MR. GASTEL:
Q. And you'll see, Ms. Marchione, that this is an e-mail correspondence from July of 2006.
Do you see that?
A. I do, yes.
Q. And it's an e-mail from Simon Diaz to you, dated July 21st, 2006, with the subject line, Hydrocodone ER.
Do you see that?
A. Yes.
Q. Do you recall receiving this e-mail?
A. No.
Q. It's forwarding an e-mail from Iris Luo, sent to a variety of folks. And it says, Hi Team.
Do you see that, ma'am?
A. I do, yes.
Q. And the e-mail says, Thank you for participating in the evaluation

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of the hydrocodone ER program from ELAN.
Did I read that correctly?
A. I think so.
Q. Do you recall this hydrocodone ER program from ELAN that's referenced in this e-mail that was forwarded to you back in 2006?
A. No, I do not.
Q. The e-mail you were forwarded goes on to state, After the recent commercial review, we have decided not to move forward with this opportunity, due to several concerns. First and foremost, the product itself doesn't possess any abuse deterrent feature and any mechanism to prevent alcohol dumping that the regulatory agency prefers to see these days for LAOs.
Did I read that correctly?
A. Yes, you did.
Q. Is the reference there to -- of "LAOs," long-acting opioids?
A. I'm deducing that it is.

Q. And was it your understanding that, at this time -- and do you believe that the "regulatory agency" there is a reference to the FDA?
MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.
THE WITNESS: Because it's in the U.S. -- because, I think ELAN is in the U.S., I'm deducing it would be the FDA.
BY MR. GASTEL:
Q. Sure. So do you recall that the FDA was concerned, back in 2006, about only approving hydro -- prescription opioids containing hydrocodone if they also contained an abuse-deterrent feature?
A. Deterrent --
MR. DIAMANTATOS: Objection to form and foundation.
Go ahead.
THE WITNESS: No. I mean, I know that abuse deterrence was

starting to be a big plus at that time.
But this is -- the person who is saying that is from the business development group, so that's not really her area of expertise. So, you know, she probably was referring to what was in the local news, or whatever.
BY MR. GASTEL:
Q. Sure. And the reason why abuse deterrents were picking up around this time was because the widespread abuse of prescription opioids throughout the country, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Argumentative. Assumes facts.
THE WITNESS: Again, I would have to assume, in general, that that was the case.
BY MR. GASTEL:
Q. And at this time in 2006, your formal employer was Cephalon,

correct?
A. That's correct.
Q. And then at some point, Cephalon merges with Teva; is that your understanding?
MR. DIAMANTATOS: Objection to form.
THE WITNESS: No. Teva acquired Cephalon.
BY MR. GASTEL:
Q. Sure. And then at that point, you ceased being a Cephalon employee and you became a Teva employee?
A. That's correct.
- - -
(Whereupon, Teva-Marchione Exhibit-43, TEVA_MDL_A_03130348, was marked for identification.)
- - -
BY MR. GASTEL:
Q. I'm going to hand you a document that we'll mark as Exhibit-43.
MR. DIAMANTATOS: Thank you.
THE WITNESS: Thank you.

BY MR. GASTEL:
Q. And I'll represent to you that this is an e-mail from Cynthia Arons dated October 9th, 2015.
It doesn't have a "to" line, but the subject line is, CCALC meeting minutes, final comment period for bylaws.
Do you see that?
A. I do see that.
Q. And I'll represent to you that this first page, ma'am, represents the metadata that's associated with this e-mail. And it shows up in your custodial file and that you're the custodian of this.
Is it possible that you were blind carbon-copied on this e-mail and that's why it's showing up in your custodial file?
MR. DIAMANTATOS: Objection. Form. Foundation.
THE WITNESS: I left the company in 2013.
BY MR. GASTEL:

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Q. Sure.
A. So I have no idea.
Q. Yeah. It kind of puzzled us, too.
Do you know what the CCALC is?
A. No. I was trying to determine that, but I don't -- I don't know.
Q. Does the term Cross-Company Abuse Liability Council ring any bells in your mind?
A. No, it doesn't.
Q. Do you ever recall reviewing meeting minutes or the bylaws for that organization?
A. No, I do not.
MR. GASTEL: Ms. Marchione, I told you I would be very short. That is the end of my examination. Subject to our previous objection and any need that we might need to have to recall you, that's all the questions we have, and we'll

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reserve.
THE WITNESS: Thank you.
VIDEO TECHNICIAN: Going off the record at 6:11 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: Back on the record at 6:14 p.m.
- - -
EXAMINATION
- - -
BY MR. DIAMANTATOS:
Q. Ms. Marchione, you were asked a series of questions this morning and afternoon by counsel with regard to your role at Cephalon, and later Teva, and your interactions with the FDA.
You're familiar with the FDA approval process insofar as what pharmaceutical companies are expected to submit as part of their new drug applications, correct?

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A. That's correct.
Q. Are you familiar with SNDAs, or supplemental new drug applications?
A. Yes, that's correct.
Q. Who gets to decide if a product is ultimately approved?
A. The FDA.
Q. Who gets to decide if a product will -- approval will be pulled?
A. FDA.
Q. Does a pharmaceutical company get to decide that?
A. No, they do not.
Q. You were asked a series of questions --
A. Excuse me. There are times when a pharmaceutical company can pull product on their own.
Q. So voluntarily a pharmaceutical company can decide to pull a product, correct?
A. That's correct, yes.
Q. But as far as the FDA approval, am I correct that the final say

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so, in terms of that approval, is, of course, the FDA?
A. Yes, that's correct.
Q. You were asked a series of questions with regard to the FDA taking issue with Cephalon and then, later, Teva with the RiskMAP program.
Do you recall those questions?
A. Yes, I do.
Q. How would you describe the dialogue that you engaged with the FDA in those instances?
A. Very interactive. Cordial. That's it.
Q. At any point in time, did you refuse to give the FDA information that they were seeking?
A. Never.
Q. At any point in time, did you refuse to attend a meeting that the FDA had requested?
A. No.
Q. Do you have any knowledge of

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anyone from your team, or at Cephalon or Teva, receiving such a request from the FDA?
A. No, not at all.
Q. To either provide information --
A. That's correct.
Q. -- or sit down for a meeting?
A. Always, we were always there.
Q. You detailed for us earlier this morning and afternoon, during the approximate 2003 to 2004 time frame, there was specific dialogue with the FDA about concerns that were raised having to do with Actiq in particular, correct?
A. That's correct.
Q. You detailed for us that there was a meeting that culminated with Cephalon asking for a sit-down and a July 12th, 2004 presentation, which in the record is Exhibit-11.
Do you recall that?

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MR. CRAWFORD: Objection. Form. Mischaracterizes.
BY MR. DIAMANTATOS:
Q. Do you recall being shown an Exhibit-11? And it should be in front of you, and if you can pull it out, that would be great.
MR. DIAMANTATOS: For the record, I'll note that it's Bates TEVA_MDL_A_01575289 through TEVA_MDL_A_01575971.
THE WITNESS: Yes.
And just to be clear, you just said that we asked for a sit-down. It was the other way around, the FDA asked us to come out.
BY MR. DIAMANTATOS:
Q. So Mr. Rappaport reached out to you, right?
And we saw that in an exhibit, with regard to the concerns that Mr. Rappaport was raising, correct?
A. That's correct.

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Q. And you acknowledged that you passed on that message to other team members of yours at Cephalon, correct?
A. That's correct.
Q. And that this culminated in a sit-down meeting with Mr. Rappaport and others from the FDA, correct?
A. That's correct.
Q. That meeting happened some time in 2004?
A. That's correct. July -- what was it? The meeting was scheduled for July 14, 2004.
Q. And that meeting, of course, occurred, and you testified about it earlier today, right?
A. Yes, I did.
Q. The approximate 682 pages that make up Exhibit-11, what is that, in Exhibit-11?
A. That was a meeting package that the FDA specifically asked for, for different pieces, that we provided prior to the meeting.

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Q. Did you assist in both the gathering of the information and, ultimately, the -- this presentation that went to the FDA?
A. Yes, I did.
Q. It starts with a letter that is addressed to Mr. Rappaport specifically, correct?
A. That's correct.
Q. We reviewed only portions of that letter earlier today during your testimony.
But to be clear, it's about a 15-page letter signed by you, correct?
A. That's correct.
Q. In that letter, you address the concerns raised by the FDA and the requested information; is that right?
A. Yes.
Q. You provide information with regard to pediatric exposure in the information that the company had compiled; is that right?
A. That's correct.

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Q. Did you describe, in that letter, details with regard to diversion, abuse and misuse?
A. Yes, we did.
Q. What is meant by "diversion"?
A. Diversion was a product taken or stolen outside of our chain, our supply chain.
Q. Did you detail, in this letter, instances that the company was aware of with regard to alleged diversion that had occurred?
A. Yes, we did.
Q. Alleged abuse?
A. Yes, we did.
Q. Alleged misuse of the product?
A. Yes, we have that information.
Q. Overdose information?
A. Yes, we have that.
Q. Death information?
A. Yes.

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Q. Off-label use?
A. Yes.
Q. And to be clear --
MR. CRAWFORD: Objection. Form.
BY MR. DIAMANTATOS:
Q. To be clear, off-label use can include where a prescription, a valid prescription, has been written by a medical professional who may be writing that script off label, correct?
A. That's correct.
Q. To your knowledge, is there any law or regulation against off-label prescription writing by a medical professional who, in his or her own professional judgment, decides to go off label and write a prescription?
A. My understanding, there's no law against that.
Q. It's off-label promotion that is not permitted, correct?
A. That's correct.
Q. The cover letter goes on to

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describe certain statistical information that the company had compiled, correct?
A. That's correct.
Q. Would you categorize -- sorry, would you characterize your letter as open?
A. Very much.
MR. CRAWFORD: Objection. Vague.
BY MR. DIAMANTATOS:
Q. How would you characterize your letter, Ms. Marchione, to the FDA?
A. Extensive. An extensive summary of the status of misuse, abuse, everything that they were concerned about.
Q. Would you call it -- any form of this letter an effort to hide the ball from the FDA?
A. Just the contrary. We were completely forthcoming, including our presentations.
Q. Is that transparency consistent with all of your

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communications that you participated in with the FDA during your entire tenure with Cephalon and later Teva?
MR. CRAWFORD: Objection to form.
THE WITNESS: I believe that it was.
BY MR. DIAMANTATOS:
Q. I just want to highlight the table of contents, which is found on Bates number 5307. It's immediately after the 15-page letter.
A. Yes.
Q. Am I correct -- and I don't want to go through each of the attachments, but counsel didn't spend a lot of time on this particular exhibit during his examination.
But am I correct that you included a number of items to supplement the letter that you submitted to the FDA in this time frame?
A. Yes, we did.
Q. Attachments included

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correspondence that you had engaged with -- prior to this occasion, with the FDA on this topic?
A. On the RMP, yes.
Q. What is an RMP?
A. The risk management program.
Q. Okay. You included the risk management program quarterly report, or at least examples of them?
A. That's correct.
Q. You included attachments that detailed pediatric exposure summary information and pediatric exposure listing information, correct?
A. That's correct.
Q. Diversion summary information?
A. That's correct.
Q. Diversion listing?
A. That's correct.
Q. Drug abuse summary information?
A. That's correct.
Q. Drug abuse listing?

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A. That's correct.
Q. Misuse summary information?
A. Yes, we did.
Q. Misuse listing?
A. Yes, we did.
Q. Overdose summary information?
A. Yes, we did.
Q. Overdose listing?
A. Yes.
Q. Fatal outcome summary information?
A. Yes.
Q. Fatal outcomes listing --
A. Yes.
Q. -- parens, spontaneous, closed parens?
A. Yes.
Q. Actiq off-label counts versus patient exposure?
A. Yes.
Q. Cephalon RMP audit report?
A. Yes.
Q. And to be clear, you

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included in this presentation the concerns that Mr. Brennan had raised, internally first with the company, and thereafter in the letter that we saw that he sent to the FDA, correct?
A. That's correct.
Q. You also included Cephalon's response to that audit report?
A. Yes, we did.
Q. Did you ever attempt to hide what Mr. Brennan had raised within the company, as far as the concerns as he perceived them?
A. No, not at all.
Q. Did you include Actiq sales training materials as part of your presentation?
A. Yes, we did.
Q. It appears as, at least based on the table of contents, that that was a very voluminous portion of the exhibit, correct?
A. Yes.
Q. And to be clear, any type of

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marketing material that was to be used by the company needed to be vetted first by you and your team, correct?
A. Any marketing that was going to be distributed to healthcare providers, yes.
Q. And that also needed to be submitted to the FDA, correct?
A. Yes, that's correct.
Q. And, of course, we heard today about the back-and-forth with regard to the FDA taking issue, potentially, with certain promotional materials and making recommendations on how the materials needed to be changed, right?
A. Yes, correct.
Q. And I think you detailed for us that in each and every one of those instances, you and your team took action to correct those materials in line with what the FDA had suggested, right?
A. Yes, we did.
Q. To your knowledge, were any

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of the materials that you submitted and the FDA ultimately approved, did they describe any type of off-label promoting or marketing?
A. We never received any feedback from the agency, once we submitted it, the final copies.
Q. According to the table of contents, you also attached a sales bulletin.
In this instance, Sales Bulletin Number 9, right?
A. Yes.
Q. Example of unbranded promotional piece?
A. Yes.
Q. Example of Actiq branded promotional piece?
A. Yes.
Q. Actiq journal articles?
A. Yes.
Q. Cephalon compliance program?
A. Yes.
Q. Regulation of pharmaceutical

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products compliance program?
A. Yes.
Q. Business ethics review questionnaire?
A. Yes.
Q. Historical overview of Actiq approval and risk management program?
A. Yes.
Q. And a number of summaries of certain media coverage having to do with Actiq, correct?
A. Yes.
Q. You also included Cephalon initiatives for risk minimization, correct?
A. That's correct.
Q. At any point in time, did you receive a warning letter from the FDA with regard to Actiq?
A. No.
MR. CRAWFORD: Objection. Vague.
BY MR. DIAMANTATOS:
Q. At any point in time in your

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tenure as regulatory -- in regulatory affairs, in any capacity, did you receive a warning letter from the FDA with regard to Actiq?
MR. CRAWFORD: Objection. Form.
THE WITNESS: No.
BY MR. DIAMANTATOS:
Q. Same question with regard to Fentora.
Did you ever receive a warning letter from the FDA with regard to Fentora?
MR. CRAWFORD: Objection. Form.
THE WITNESS: No.
BY MR. DIAMANTATOS:
Q. Did you ever receive what you referred to earlier as an NOV?
Do you recall that answer that you gave earlier?
A. We had one NOV letter. And, I'm sorry, I didn't remember if it was for Treanda --

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Q. What is an NOV?
A. A notice of violation, which means not as significant as a warning; the FDA wants you to correct an issue.
Q. At any point in time, did the FDA pull its approval of Actiq?
A. No.
Q. At any point in time, did the FDA pull its approval of Fentora?
A. No.
Q. To be clear, we talked about Fentora's approval, and I know counsel went through the timeline for you, and we were able to pinpoint, through a number of documents, including the timeline, that the FDA approved Fentora some time in 2006, correct?
A. That's correct.
Q. Was that after this meeting that we talked about in July 12th of 2004 where the FDA --
A. Yes.
Q. -- had concerns?
A. Yes, it is.

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Q. To be clear, the indication for Actiq was identical to the indication for Fentora, correct?
A. That's correct.
Q. Did the Fentora approval come after the concerns raised in Mr. Brennan's letter with regard to Actiq?
A. Yes, they did.
Q. Did they come after the concerns raised by Dr. Rappaport in his phone call to you and in his correspondence to you?
A. Yes, it did.
Q. Going back to the notion of black box warnings.
Counsel covered with you what a black box warning is, and you described that.
Am I correct that all of the marketing materials that were used with Actiq and Fentora included that black box warning?
A. Yes, it did.
Q. Isn't a black box warning a

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form of an educational piece?
MR. CRAWFORD: Objection. Vague.
BY MR. DIAMANTATOS:
Q. Let me be clear.
Does a black box warning -- the marketing materials, do they need to contain information about the label indication?
Is that a yes?
A. Yes, it is.
Q. Okay. Do they need to contain information about the benefits of a product?
A. Yes. But the FDA wants you to put safety first.
Q. Safety goes first, right?
A. Yes.
Q. And every single piece of marketing has to include safety and risk information, right?
A. That's correct.
Q. You described earlier for us that you participated in training with

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sales individuals.
The training that you participated in with sales individuals, what, if anything, did you describe to them needed to be done in terms of their education of doctors that they were visiting?
A. So my part of the training was to review the RiskMAP, I went through all the elements, what the FDA was concerned about, how we had to report information, and the specific details.
Q. Counsel entered an exhibit and asked you about the 2008 guilty plea that the company entered into.
Do you recall that?
A. Yes, I do.
Q. You mentioned -- in response, you made reference to a CIA.
Do you remember that?
A. Yes, I do.
Q. Were you referring to a corporate integrity agreement?
A. Yes, I was.

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Q. Am I correct that you were aware that there was a corporate integrity agreement in place, correct?
A. Yes, I was.
Q. Did you have to sign, acknowledging that you were aware of the corporate integrity agreement and exactly what it spelled out the company needed to do?
A. Yes, I did.
Q. Do you recall how long of a time period the corporate integrity agreement covered?
A. Not -- not --
Q. Was it multiple years?
A. It was multiple years.
Q. Did you and members of your team follow exactly what the corporate integrity agreement spelled out the company needed to do?
A. I can only speak for myself. But yes.
Q. To your knowledge, did people on your team also abide by what

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the corporate integrity agreement called --
A. To my knowledge.
Q. At any point in time after 2008 and the guilty plea referenced by counsel, did the FDA pull approval for Fentora?
A. No, it did not.
Q. It might have not been pertinent at this time, but was Actiq's approval ever pulled?
A. No, it was not.
Q. There was a description about a TIRF REMS program in the afternoon portion of your testimony.
Can you please explain what a TIRF REMS program is? Do you know what the acronym stands for?
A. Actually, I don't -- I don't remember.
Q. Okay. What is it? What's a TIRF REMS program?
A. To my recollection, again, the FDA started requesting manufacturers

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of short-acting, long-acting programs to discuss, in groups, what the requirements were in order to have consistency and not to have extreme redundancy then be imposed upon physicians, in terms of -- in terms of impacting the areas of distribution and the whole chain of the product.
Q. You mentioned "chain of the product."
Am I correct that only certain doctors are authorized to write scripts for products that fall within the TIRF's category?
A. I believe having a controlled product limits the prescribing of who can -- what levels can prescribe.
Q. How about patients; patients need to sign up for the TIRF REMS program as well, don't they?
A. My recollection, that was what they were trying to initiate, yes.
Q. Distributors?
A. Yes.

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Q. And that information is gathered and, of course, provided to the FDA, right?
A. That was my recollection.
Q. And am I correct that all of Teva and Cephalon's opioid medications that we've been discussing today, including Actiq and Fentora, were FDA approved and only available through a prescription?
A. Yes.
Q. Am I correct that the FDA approved both of these opioid medications, notwithstanding the risks?
A. Yes.
Q. Am I correct that the prescribing information and patient labels provide information regarding risks and benefits of the prescription opioid?
A. Yes.
Q. Including the black box warning that counsel walked you through earlier this afternoon?

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A. Yes.
Q. And that black box warning includes information about risk of addiction, correct?
A. That's correct.
MR. DIAMANTATOS: I don't have any further questions for the witness. Thank you, Ms. Marchione.
THE WITNESS: Thank you.
MR. CRAWFORD: I have a couple.
How many minutes do I have?
VIDEO TECHNICIAN: Nineteen.
- - -
EXAMINATION
- - -
BY MR. CRAWFORD:
Q. Counsel asked you about a corporate integrity agreement that was entered into by the company with the U.S. government, right?
A. Correct.
Q. Is it your understanding

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that that was a -- what's your understanding of why they were required to enter into a corporate integrity agreement?

MR. DIAMANTATOS: Objection. Form. Calls for a legal conclusion. Foundation.

THE WITNESS: My recollection, reading and signing it, is that there were violations of marketing and that the DOJ, I think, or -- I mean, the Justice Department or -- I can't remember the exact details -- but wanted to have oversight of the company for corrective action.

BY MR. CRAWFORD:

Q. And corrective action because, previously, the government had found that the company was marketing products off label, correct?

MR. DIAMANTATOS: Objection. Form. Foundation.

THE WITNESS: Going back to

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the document you showed me, that appeared to be the case, yes.

BY MR. CRAWFORD:

Q. And it included Actiq, off-label promotion of Actiq, correct?

MR. DIAMANTATOS: Same objections.

THE WITNESS: That's what it said in that document, yes.

BY MR. CRAWFORD:

Q. And counsel had asked you about doctors being able to prescribe off label, prescribe products off label.

But a company -- a pharmaceutical company is not allowed to promote a drug off label, in other words, for nonindicated uses, correct?

A. That's correct.

Q. And, in fact, when the FDA approved Actiq and Fentora, it approved it on a condition that the RiskMAPs be adhered to, to ensure that the drugs be used safely, right?

MR. DIAMANTATOS: Objection.

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Form.

THE WITNESS: The RiskMAP was to support the commercialization of the product in a safe way, yes.

BY MR. CRAWFORD:

Q. And they were integral to the approval, were the words of the FDA, right?

A. Yes, that's correct.

Q. And you're aware -- strike that.

If you could pick up Exhibit-11. This was the July 12th, 2004 submission that you had made to the FDA prior to the July 14th meeting that counsel asked you about just now, correct?

A. Yes.

Q. And this is information that the FDA specifically requested be provided to it before the meeting, correct?

A. Yes.

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But I'd have to look at, did we add anything additional? I just don't remember if we had additional information in this.

Q. But much of it was actually requested by the FDA?

A. Yes.

Q. And then, in fact, when the information was given to the FDA, they and DDMAC expressed great alarm over what they were seeing in your packet that you gave, right?

MR. DIAMANTATOS: Objection. Form. Vague.

THE WITNESS: So we had two meetings. The initial meeting, which -- where DDMAC was part of -- actually, there were approximately 60, 70 people from FDA in the room. There was no -- there was no negative feedback during that discussion, and they thanked us for coming.

The secondary meeting with

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DDMAC, who, in their meeting minutes, showed concern about the -- we went through the information. They expressed their concerns about some of the marketing targets.
BY MR. CRAWFORD:
Q. Right. So this packet, which is, you know, at least a couple of inches thick, was submitted two days prior to the meeting, right?
A. Oh, God, I'd have to -- I'd have to check. I don't know.
Q. The meeting was July 14th, right? That's what it references --
A. Okay. And so the submission --
Q. -- on the letter, right?
A. Submission date was the 12th, that's correct.
Q. And it references a July 14th meeting, right?
A. That's correct.
Q. You said there were 60

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people from the FDA at the meeting?
A. Yeah, approximately.
Q. And then you went through the meeting minutes, and those minutes accurately reflected what happened at the meeting, right?
MR. DIAMANTATOS: Objection to form. Mischaracterizes the witness's testimony.
THE WITNESS: Right. There were two -- there were two different meeting minutes.
BY MR. CRAWFORD:
Q. Meaning the July 14th minutes --
A. Yes, yes.
Q. -- that the FDA provided?
A. Yes.
Q. Those were accurate?
A. I believe so.
Q. And the FDA did express a number of concerns about the off-label marketing in that meeting, correct?
MR. DIAMANTATOS: Objection.

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Form.
Go ahead.
THE WITNESS: During the meeting, they -- I mean, there were questions. But it was -- it was very -- it was really one-sided where we presented everything. And then we got the meeting minutes that reviewed it.
But during that meeting, they asked questions, there were concerns. But they didn't -- they didn't, at the end of it, say, we're really -- a lot of issues or problems.
We did hear that at the DDMAC meeting. So that was where it was more expressed.
BY MR. CRAWFORD:
Q. Right. The DDMAC was very concerned about these materials you had submitted, correct?
MR. DIAMANTATOS: Objection. Form. Calls for speculation.

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THE WITNESS: We reviewed those. So however they -- I mean, that's the -- that's how you -- they were concerned about the issues, yes.
BY MR. CRAWFORD:
Q. So if you pull up Exhibit-22, these concerns were expressed --
A. I believe they were.
Q. -- at length in these minutes that were provided at the meeting, correct? If you can pull that up.
A. Is it the DDMAC one?
Q. Right.
A. Yes.
Q. If you can pull those out and look at the second -- second page at the top.
A. The one doesn't seem to have a label, by the way.
Q. It doesn't?
A. It may be his copy, I don't

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know.
Q. We'll have to check that, then.
It says, DDMAC agreed to meet with Cephalon and also stated that it would like to discuss various concerns DDMAC had regarding the promotion of Actiq, including concerns regarding information about Cephalon's promotion that was provided by Cephalon during the July 14th, 2004 joint division meeting and in Cephalon's briefing package for the July 14th, 2004 meeting.
They are referencing the -- the July 12th submission was the briefing package you provided, right?
A. That's correct.
Q. And so once they had a chance to look through that, they were meeting with you here to express their concerns about what you provided them in the packet?
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for

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speculation. Asked and answered.
THE WITNESS: This is a subsection of FDA, this is the promotion review section.
BY MR. CRAWFORD:
Q. All right. So on Number 2, that first sentence there saying that, DDMAC expressed concerns that, as indicated by Cephalon's briefing package for and presentation at the July 14th, 2004 meeting, the company targets physicians for Actiq promotion purely based on the number of opioid prescriptions they write, and the company is making no effort to screen these targeted physicians to determine whether they treat cancer patients and, thus, would be appropriate to be detailed on Actiq, given its limited indication.
So the briefing packet and the presentation actually raised a serious concern by DDMAC, would you agree, about the targeting of physicians?
A. That's what it says here,

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yes.
MR. DIAMANTATOS: Objection. Form. Foundation. Calls for speculation. Asked and answered.
BY MR. CRAWFORD:
Q. All right.
MR. CRAWFORD: But I'm just following up on your questions here.
BY MR. CRAWFORD:
Q. On 3, DDMAC did express concerns about the briefing package and its presentation instructing sales force -- its sales force to open sales calls in a manner that fails to focus on Actiq's limited indication and instead focuses on the physician's treatment of breakthrough pain in general, thus, inappropriately broadening physician's perceptions of the drug's use to treat -- the treatment of all forms of BTP, rather than BTCP in the indicated population, correct?
MR. DIAMANTATOS: Objection.

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Form. Foundation. Calls for speculation. Document speaks for itself. Asked and answered.
THE WITNESS: That's what it says here.
And there's also a response from Cephalon that says that we trained our sales representatives to always provide the label indication for Actiq during its sales calls and promote only Actiq's labeled education. It educates them on therapeutic area, pain in general.
BY MR. CRAWFORD:
Q. We'll go into -- directly to 4 and 5. Again, you agree with me that DDMAC is expressing concerns about information Cephalon has provided in the briefing package, right?
MR. DIAMANTATOS: Objection. Form. Foundation. Asked and answered.
THE WITNESS: Yes.

BY MR. CRAWFORD:

Q. So in sum, the FDA had requested much of the information, you would agree, in the briefing package.

And then when they had time to look at it, and they had that meeting, DDMAC, on August 30th, they expressed a number of concerns about what they were seeing in that package, right?

MR. DIAMANTATOS: Same objections.

THE WITNESS: That's what it says here, yes.

MR. CRAWFORD: That's all I have. Thank you.

- - -

(Whereupon, Teva-Marchione Exhibit-39, TEVA_MDL_A_074679522, was marked for identification.)

- - -

VIDEO TECHNICIAN: This ends today's deposition. We're going off the record. The time is 6:43 p.m.

- - -

(Whereupon, the deposition concluded at 6:43 p.m.)

- - -

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

Amanda Maslynsky-Miller
Certified Realtime Reporter
Dated: January 21, 2019

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After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

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ERRATA

PAGE	LINE	CHANGE/REASON

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 551, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
CAROL MARCHIONE DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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